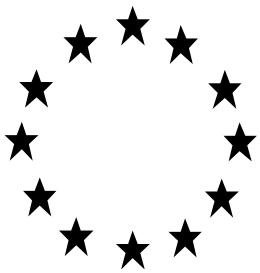
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

RISK ASSESSMENT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS



Super

Product type 04

Active chlorine released from sodium hypochlorite

Case Number in R4BP: BC-JL045805-30

Evaluating Competent Authority: Finland

Date: [13/11/2020]

Amended 19/10/2023

Changes history table

Application type	refMS /eCA	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment / renewal)	Chapter/ page
NA-APP	*FI*	BC-JL045805-30	13.11.2020	*Initial assessment*	
NA-ADC	*FI*	BC-LM088443-23	19.10.2023	*Addition of two manufacturers of the active substance and the addition of a formulator of the product.*	2.1.1.3/p.6 2.1.1.4/p.7

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1 CONCLUSION

The Finnish CA proposes the authorisation of the biocidal product “Super” for disinfection of milk tanks/milking machines by cleaning in place with circulation (CIP) (PT4) for professional use under Regulation (EU) No 528/2012 (BPR).

The biocidal product contains an active substance “Active chlorine released from sodium hypochlorite” at the concentration of 4% (w/w). When using the product according to the instructions for use and applying specific risk mitigation measures as indicated in the SPC, the product will be efficacious and will not pose an unacceptable risk to human and animal health nor to the environment. A classification according to Regulation (EC) No 1272/2008 is necessary. Detailed information on classification and labelling is provided in chapter 2.1.3.

Physico-chemical properties
The physico-chemical properties have been assessed and concluded to be acceptable (see chapter 2.2.2). The content of active substance decreases during storage and the content of the active substance residue increases during storage. Therefore, a shelf life of 9 months has been accepted with confirmed efficacy.
The physical hazards have been assessed. The product is classified as corrosive to metals, no other hazards have been identified (see chapter 2.2.3).
The analytical methods are validated for determination of the active substance as well as the active substance residue in the product (see chapter 2.2.4). Analytical methods for monitoring are not required.

Efficacy
The product has been shown to be efficacious against bacteria and yeast in the intended use disinfection by “cleaning in place with circulation“ of milking machines and milk cooling tanks. Efficacy has been shown for a product at the time of manufacture and at the end of shelf-life.

Risk assessment for human health
The substance sodium hydroxide has been identified as substance of concern for the human health.

The human health risk assessment for the professional user of this product is based on the active substance as well as on the substance of concern. The human health risk assessment for the general public is based on the active substance residue.
The human health risk assessment has been carried out for professional use of the product (see chapter 2.2.6) for intended use (see chapter 2.2.1).

Based on the risk assessment it is unlikely that the intended use cause any unacceptable acute or chronic risk to professional users, bystanders and residents. Regarding professional users health protection, there are no objections against the intended use if the directions for use according to chapters 2.1.4 and 2.1.5 are followed.

Risk assessment for environment
No unacceptable risks have been identified in the risk assessment for environment when the emissions are discharged to the municipal sewage treatment plant (STP). Based on fast degradation of active chlorine in sewer, the amount of active chlorine reaching the STP or other environmental compartments is negligible. In addition, chlorate as relevant impurity was assessed qualitatively for all environmental compartments and for abstraction of drinking water from surface water. No unacceptable risk for environment or for abstraction of drinking water will be likely when chlorate is present as an impurity in the Super product.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	Country (if relevant)
Super Universal alka	Finland

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	Name	DeLaval NV
	Address	Industriepark-Drongen 10, 9031 Gent, Belgium
Authorisation number	FI-2020-0022	
Date of the authorisation	13/11/2020	
Expiry date of the authorisation	12/11/2030	

2.1.1.3 Manufacturer of the product

Name of manufacturer	DeLaval NV
Address of manufacturer	Industriepark-Drongen 10, 9031 Gent, Belgium
Location of manufacturing sites	Industriepark-Drongen 10, 9031 Gent, Belgium

Name of manufacturer	DeLaval Operations Sp. z.o.o
Address of manufacturer	Ul. Robotnicza 72, 53-608 Wroclaw, Poland
Location of manufacturing sites	Ul. Robotnicza 72, 53-608 Wroclaw, Poland

2.1.1.4 Manufacturer(s) of the active substance

Active substance	Active chlorine released from sodium hypochlorite
Name of manufacturer	Inovyn
Address of manufacturer	Olympiadenlaan 20 1140 Brussels, Belgium
Location of manufacturing sites	Site 1: Inovyn Manufacturing Belgium SA Rue Solvay 39 5190 Jemeppe-sur-Sambre, Belgium Site 2: Inovyn Manufacturing Belgium NV Scheldelaan 480 – Haven 647 2040 Antwerpen, Belgium

Active substance	Active chlorine released from sodium hypochlorite

Name of manufacturer	Vynova Belgium NV
Address of manufacturer	Heilig-Hartlaan 21 3980 Tessenderlo, Belgium
Location of manufacturing sites	Heilig-Hartlaan 21 3980 Tessenderlo, Belgium

Active substance	Active chlorine released from sodium hypochlorite
Name of manufacturer	PCC Rokita SA
Address of manufacturer	Ul. Sienkiewicza 4, 56-120 Brzeg Dolny, Poland
Location of manufacturing sites	Ul. Sienkiewicza 4, 56-120 Brzeg Dolny, Poland

Active substance	Active chlorine released from sodium hypochlorite
Name of manufacturer	Nobian Industrial Chemicals BV
Address of manufacturer	Van Asch van Wijckstraat 53, 3811 LP Amersfoort, Netherlands
Location of manufacturing sites	Elektrolysestraße 1, 06749 Bitterfeld, Gemany Hauptstraße 47, 49479 Ibbenbüren, Germany

2.1.2 Product composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Hypochlorous acid, sodium salt
IUPAC or EC name	Sodium hypochlorite
EC number	231-668-3
CAS number	7681-52-9
Index number in Annex VI of CLP	017-011-00-1
Minimum purity / content	Active substance assessment report: ≤180 g/kg; ≤18% (w/w). Specification of the manufacturers: aqueous solution with an available (active) chlorine concentration ≥12 - ≤ 16% (w/w) (typical 13.5% (w/w))
Structural formula	NaClO 

2.1.2.2 Candidate(s) for substitution

Not applicable

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Active chlorine released from sodium hypochlorite	Sodium hypochlorite	Active substance	7681-52-9	231-668-3	4.0 (as active chlorine)
Sodium hydroxide	Sodium hydroxide	pH regulator Substance of concern	1310-73-2	215-185-5	10.0
Full composition details are considered confidential. This information can be found in the confidential annex 3.6					

2.1.2.4 Information on technical equivalence

According to statements received from the manufacturers of the active substance 'active chlorine released from sodium hypochlorite', i.e. Inovyn and Vynova (both members of the Euro Chlor Sodium Hypochlorite Registration Group), the sources of the substance are the same as those evaluated for inclusion in the Union list of approved active substances under Regulation No. 528/2012. Therefore, no assessment of technical equivalence is needed.

2.1.2.5 Information on the substance(s) of concern

Sodium Hydroxide is a substance of concern for human health contributing to the classification of Super as Skin Corr. 1C. Occupational exposure limit of 2 mg/m^3 is also given for sodium hydroxide. No substances of concern have been identified for environment.

2.1.2.6 Information on endocrine disrupting properties

ED properties of active substance are assessed during active substance approval. According to the assessment report of Active chlorine released from sodium hypochlorite PT4 (2017) based on the available experimental results, there is no indication that active chlorine released from sodium hypochlorite affects the endocrine system. There are no indications of endocrine disruptive properties of non-active substances (co-formulants) in the product either (for more details please see the confidential annex). Hence, based on the current knowledge the product is not an endocrine disruptor.

2.1.2.7 Type of formulation

SL – soluble concentrate

2.1.3 Hazard and precautionary statements

Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008

Classification	
Hazard category	Acute Tox. 4 (oral) Skin Corr. 1C Eye Dam. 1 Aquatic Acute 1 Aquatic Chronic 2 Met. Corr. 1
Hazard statement	H302 - Harmful if swallowed H314 - Causes severe skin burns and eye damage H318 – Causes serious eye damage H400 - Very toxic to aquatic life H411 – Toxic to aquatic life with long lasting effects H290 - May be corrosive to metals
Labelling	
Hazard pictograms	 GHS05  GHS07  GHS09
Signal words	Danger
Hazard statements	H290 - May be corrosive to metals H302 - Harmful if swallowed H314 - Causes severe skin burns and eye damage H410 - Very toxic to aquatic life with long lasting effects
Precautionary statements	P102 - Keep out of reach of children P273 - Avoid release to the environment P280 - Wear protective gloves/protective clothing/eye protection/face protection P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell P303 + P361 + P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 - Immediately call a POISON CENTER/ doctor. P501 - Dispose of contents/container in accordance with local regulations
Note	Contains: Sodium hydroxide, sodium hypochlorite

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – Disinfection of milk tanks/milking machines by cleaning in place with circulation (CIP)

Product Type	PT04
Where relevant, an exact description of the authorised use	Disinfection by “cleaning in place with circulation“ of milking machines and milk cooling tanks.
Target organism (including development stage)	Bacteria & Yeasts
Field of use	Indoor
Application method(s)	Cleaning in place with circulation
Application rate(s) and frequency	Dosing: 1.75 % v/v (use dilution) Frequency: The time between applications will depend on the frequency of cleaning of the milking machines and cooling tanks (maximal 2x/day, after each milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Please see the section 2.1.7.

2.1.4.2 Use-specific instructions for use

1. Empty the installation of all residual milk traces.
2. Pre-rinse with water (40-45°C).
3. Dose 1.75% v/v Super (1.75 dL/10 L water) in warm water between 60 and 85°C.
4. Circulate solution for 10 minutes. Always keep water temperature above 40°C. Check cluster and water flow.
5. Remove the disinfection solution and rinse the equipment with clean cold water.
6. Allow the installation to dry.

2.1.4.3 Use-specific risk mitigation measures

The following personal risk mitigation measures shall be applied unless they can be replaced by technical and/or organisational measures:

- For handling the concentrated product, chemical resistant gloves (EN 374), protective clothing (at least type 3) and eye protection (EN 166) must be worn.

2.1.4.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

No use-specific measures, see section 2.1.5.3

2.1.4.5 Where specific to the use, the instructions for safe disposal of the product and its packaging

No use-specific instructions, see section 2.1.5.4

2.1.4.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

No use-specific conditions, see section 2.1.5.5

2.1.5 General directions for use

2.1.5.1 Instructions for use

No general directions for use, see Section 2.1.4 for the specific use.

2.1.5.2 Risk mitigation measures

Do not discharge wastewater containing the product to an on-site wastewater treatment system.

2.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

DIRECT / INDIRECT EFFECTS
No known adverse effects.

FIRST AID INSTRUCTIONS
Eye contact: Immediate medical attention is required. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing.
Skin contact: Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes.
Ingestion: Immediate medical attention is required. Remove from exposure, lie down. Clean mouth with water and afterwards drink plenty of water. Do not induce vomiting. Never give anything by mouth to an unconscious person. Call a physician or Poison Control Center immediately.
Inhalation: Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician or Poison Control Center immediately.

EMERGENCY METHODS TO PROTECT THE ENVIRONMENT
Prevent further leakage or spillage if safe to do so.
Dam up. Collect spillage. Soak up with inert absorbent material. Prevent product from entering drains. Keep in suitable and closed containers for disposal.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Unused product and its packaging should be disposed of in accordance with local regulations.

2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

Storage: Store upright in the tightly closed original container. Protect from direct light, temperatures above 30°C and frost. If the product is frozen, thaw in a warm environment and mix well before use. Shelf-life: 9 months.

2.1.6 Other information

/

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Can	5L	HDPE	Screw cap, HDPE	Professional	Yes
Can	10L	HDPE	Screw cap, HDPE	Professional	Yes
Can	20L	HDPE	Screw cap, HDPE	Professional	Yes
Can	25L	HDPE	Screw cap, HDPE	Professional	Yes
Drum	60L	HDPE	Screw cap, HDPE	Professional	Yes
Drum	200L	HDPE	Screw cap, HDPE	Professional	Yes
IBC	1000L	HDPE	Screw cap, HDPE	Professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

Data submitted for this product dossier is listed in the list of studies in Annex 3.1.

2.1.8.2 Access to documentation

The applicant, DeLaval NV, is the owner of all data submitted with regard to the tests performed with Super. So for those studies no letter of access is submitted.

A letter of access to the data on the active substance 'Active chlorine released from sodium hypochlorite' issued by [redacted] is submitted.

2.2 Assessment of the biocidal product

2.2.1 Intended use(s) as applied for by the applicant

Table 2. Intended use # 1 – Disinfection of milk tanks/milking machines by CIP with circulation

Product Type(s)	PT04		
Where relevant, an exact description of the authorised use	Disinfection by “cleaning in place with circulation“ of milking machines and milk cooling tanks.		
Target organism (including development stage)	Bacteria & Yeasts		
Field of use	Indoor		
Application method(s)	Cleaning in place with circulation		
Application rate(s) and frequency	Dosing: 1.75 % v/v Frequency: The time between applications will depend on the frequency of cleaning of the milking machines and cooling tanks (maximal 2x/day, after each milking).		
Category(ies) of user(s)	Professional		
Pack sizes and packaging material	Type	Material	Size
	Can	Plastic: HDPE	5L
	Can	Plastic: HDPE	10L
	Can	Plastic: HDPE	20L
	Can	Plastic: HDPE	25L
	Drum	Plastic: HDPE	60L
	Drum	Plastic: HDPE	200L
	IBC	Plastic: HDPE	1000L

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual	Undiluted product	Liquid	Not a study
Colour at 20 °C and 101.3 kPa	Visual	Undiluted product	Pale yellow	Not a study
Odour at 20 °C and 101.3 kPa	Smelling	Undiluted product	Slight chlorine	Not a study
Acidity / alkalinity	CIPAC MT 75.3 (pH)	1% w/w solution	pH 12.35	Physical/chemical properties of Super (Formulation 102), REP: FR 2017-PC-006, S. Leibowitz, 2017
	CIPAC MT 75.3 (pH)	Undiluted product Lot: A195150200	pH 13.85 (calibration buffers pH 4, 7, 10) pH 13.70 (calibration buffers pH 7, 10, 12)	pH of Super, Additional information, RA200013a – Annex 1, S. Tanghe, 2020
	CIPAC MT 75.3 (pH)	1% w/v solution Lot: A195150200	pH 12.46 (calibration buffers pH 4, 7, 10) pH 12.45 (calibration buffers pH 7, 10, 12)	pH of Super, Additional information, RA200013a – Annex 1, S. Tanghe, 2020
	Comment of rMS: As the highly alkaline pH of the undiluted product and 1% dilution (w/v) are out of the calibration range of the pH meter the results are to be taken as approximate.			
	CIPAC MT 191 (alkalinity) The test substance is titrated to an endpoint of pH 8.5	Undiluted product	Alkalinity: 10.13 %w/w as NaOH and 7.84 % as Na_2O	Physical/chemical properties of Super (Formulation 102), REP: FR 2017-PC-006, S. Leibowitz, 2017
Relative density / bulk density	USP test method with modificati	Undiluted product	Average relative density (D_4^{20}): 1.180	Physical/chemical properties of Super

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	ons according to EC method A.3			(Formulation 102), REP: FR 2017-PC-006, S. Leibowitz, 2017
Storage stability test – accelerated storage	/	/	DATA WAIVING: The label contains the warning: "Protect from temperatures above 30°C." Therefore, accelerated storage stability studies were not performed. In addition, the long term storage stability test has been performed on the product.	/
Storage stability test – long term storage at ambient temperature	pH (1% solution): similar to CIPAC MT 75.3 Active and Total Alkalinity: similar to CIPAC MT 191 Density: 2.2.5. Relative density, Eur. Ph. VII Active chlorine: titration	Undiluted product	Storage 9 months at 25°C and 60% R.H. in HDPE (5 L): *) Visual inspection of appearance of the product and the packaging for leakage or deformation. The product comply with the specification. No leakage nor deformation was observed. Batch 1046503 Property / TOM / 9MO Appearance* / conf / conf Density (g/ml) / 1.179 / 1.176 pH (1%) / 12.1 / 12.2 Active alkalinity(% w/w) as Na_2O / 7.5 / 7.4 Total alkalinity(% w/w) as Na_2O / 9.50 / 8.39 Av chlorine (%) / 4.05 / [redacted] Batch 1047103 Property / TOM / 9MO Appearance* / conf / conf Density (g/ml) / 1.180 / 1.178 pH (1%) / 12.0 / 12.2 Active alkalinity(% w/w) as Na_2O / 7.4 / 7.4	Super stability - RA180335b; F. Goudezeune, 2018 Stability of Super, Additional information, RA200013a – Annex 2, M. Van Nieuwenhove

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Total alkalinity(% w/w) as Na_2O 9.45 8.29 Av chlorine (%) 4.11 [redacted] Batch 1135108 Property TOM 9MO Appearance* conf conf Density (g/ml) 1.178 1.180 pH (1%) 12.5 11.7 Active alkalinity(% w/w) as Na_2O 7.5 7.5 Total alkalinity(% w/w) as Na_2O 9.52 8.83 Av chlorine (%) 4.01 [redacted]	
	Sodium chlorate: Ionic Chromatography method	Undiluted product	Storage 9 months at 25°C and 60% RH in HDPE: Batch A173720700 Property TOM 9MO % Av chlorine 4.02 [redacted] % $ClO3^-$ 0.155 % NaClO3 0.197	Test report: Validation of an IC method for the quantification of the sodium chlorate content in the test item "Super"– S-2017-03467; M.G. Guiso, 2017 AND Determination of the sodium chlorate content in the test item "Super" - STULV18AA 0457-1; M.G. Guiso, 2018

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	Weight change		The HDPE packagings used for Super are UN approved for class 8 substances, packaging group III, shown to be compatible with chemical products. Therefore, weight change during the stability study has not been investigated.	Statement, Additional information on Super, RA200013a, Feb2020
	Dilution stability, CIPAC MT 41	1.75 % v/v (use dilution)	Batch A173720700 Fresh product (0m): 30 min: slightly cloudy with no sedimentation or separation 18 h: clear with a trace of sedimentation Aged product (9m) 30 min: flocculation layer of about 13 ml 18 h: flocculation layer compacted to about 2 ml, with clear liquid above. See also the endpoint of Dilution stability	Dilution stability of Super; A.Vancoillie, 2017 Report dilution stability of SUPER; S.Tanghe, 2018

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Storage stability test – low temperature stability test for liquids	/	/	DATA WAIVING: The label contains the warning: "Protect from frost." Therefore, cold storage stability studies were not performed. A freeze thaw cycle study (3 cycles) was performed demonstrating that the product may be frozen and thawed several times without any effect on the product quality: Property / Before conf / After conf Appearance / conf / conf Density (g/ml) / 1.180 / 1.180 pH (1%) / 12.2 / 12.2 Active Alkalinity (% w/w) as Na_2O / 7.5 / 7.2 Total alkalinity (% w/w) as Na_2O / 9.54 / 9.11 Av chlorine (%) / 4.12 / 3.90	For freeze-thaw cycling study: Super stability - RA180335b; F. Goudezeune, 2018
Effects on content of the active substance and technical characteristics of the biocidal product - light	/	/	DATA WAIVING: Super is packaged in UN-approved High-Density Polyethylene (HDPE) cans closed with HDPE screw caps. These packaging materials have been approved and commercially used for over 10 years for the packaging and storage of Super. The cans and drums are blue (5L, 10L, 20L, 25L, 60L and 200L) and protect the product from exposure to light (UV light protected). The IBC are white and are also UV light protective. It is also indicated on the labels that products should be stored in the tightly closed original container, protected from direct light and high temperatures.	/

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Effects on content of the active substance and technical characteristics of the biocidal product – temperature and humidity	/	/	Not applicable. The label of Super clearly states that the product should be stored upright in the tightly closed original container, protected from direct light, temperatures above 30°C and frost. See also the endpoints of long term storage stability and low temperature stability.	/
Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material	/	/	All materials used for packaging of Super are made of high-density polyethylene (HDPE) including the drums, screw caps and seals. Drums are UN-approved. The packaging materials are standard containers for the packaging of chemical products and are chemically compatible with Packaging Group III products such as Super. See also the endpoint of long term storage stability. These studies were all performed with HDPE containers with identical composition as the packaging used for commercial purposes. There were no signs of interaction between the packaging materials and the product (no leakage or deformations).	/
Wettability	/	/	Not applicable, Super is not a solid formulation to be dispersed or dissolved in water	/
Suspensibility, spontaneity and dispersion stability	/	/	Not applicable, Super is not a wettable powder, suspension concentrate, flowable concentrate for seed treatment which are diluted for use, capsule suspensions, water dispersible granules nor water dispersible tablet.	/

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Wet sieve analysis and dry sieve test	/	/	Not applicable, Super is not a wettable powder, suspension concentrates including those for seed treatment and oil-based, water dispersible granules and water dispersible powder for slurry seed treatment, aqueous capsule suspensions, dispersible concentrates, suspo-emulsions, water-soluble and dispersible tablets, or emulsifiable granules and powders	/
Emulsifiability, re-emulsifiability and emulsion stability	/	/	Not applicable, Super is not a emulsifiable concentrate, emulsion, oil in water and microemulsion	/
Disintegration time	/	/	Not applicable, Super is not a soluble tablet or water dispersible tablet	/
Particle size distribution, content of dust/fines, attrition, friability	/	/	Not applicable, Super is not a suspension concentrate, suspension concentrate for seed treatment, aqueous capsule suspension nor an oil dispersion	/
Persistent foaming	CIPAC MT 47.1	1.75% v/v (use dilution)	No foam after 1 minute time point.	Persistent foam test of Super, A. Vancoillie, 2017
Flowability/Pourability/Dustability	/	/	Not applicable, Super is not a water dispersible granule, water soluble granule, granule or emulsifiable granule, suspension concentrate, aqueous capsule suspension, suspo-emulsion oil-in-water emulsion and similarly viscous formulation	/
Burning rate — smoke generators	/	/	Not applicable, Super is not a smoke generator	/
Burning completeness — smoke generators	/	/	Not applicable, Super is not a smoke generator	/

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Composition of smoke — smoke generators	/	/	Not applicable, Super is not a smoke generator	/
Spraying pattern — aerosols	/	/	Not applicable, Super is not an aerosol	/
Physical compatibility	/	/	DATA WAIVING: This data requirement is not relevant to Super and its intended use. Super is not to be used with other substances, mixtures or biocidal or non-biocidal products (e.g dyes).	/
Chemical compatibility	/	/	DATA WAIVING: This data requirement is not relevant to Super and its intended use. Super is not to be used with other substances, mixtures or biocidal or non-biocidal products (e.g dyes).	/
Degree of dissolution and dilution stability	CIPAC MT 41	1.75 % v/v (use dilution)	Freshly manufactured product:30 min: slightly cloudy with no sedimentation or separation. 18h: clear with a trace of sedimentation. Aged product (9m): 30 min: a flocculation layer of about 13 mL. 18h: the flocculation layer compacted to about 2 mL, with clear liquid above. The product use does not foresee storage of diluted solutions. Dilution of the concentrate occurs only immediately before use and circulation (Cleaning in Place by Circulation in a closed system; mainly with automated dosing) and the product is not to be used as a spray. Furthermore, the diluted product is constantly in circulation, preventing sedimentation to occur.	Dilution stability of Super; A.Vancoillie, 2017 Report dilution stability of SUPER; S.Tanghe, 2018

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Surface tension	EC Method A.5	1.75% v/v (use dilution)	67.5 mN/m at 20°C Product is not surface-active.	Determination of Surface Tension on the Sample Super, 1801160, A. Mazzei, 2018
Viscosity	OECD 114	Undiluted product	2.75 cP at 20°C and 2.29 cP at 40°C at 50 rpm, using an UL adapter	Physical/chemical properties of Super (Formulation 102), REP: FR 2017-PC-006, S. Leibowitz, 2017

Conclusion on the physical, chemical and technical properties of the product

The biocidal product Super is a clear, pale yellow liquid with slight chlorine odour and with a highly alkaline pH of 13.85 (undiluted product) and alkalinity of 10.13% w/w (as NaOH, undiluted product). The physical properties of the product have been analysed and are evaluated to be suitable for use.
An acceptable stability of Super has been demonstrated for 9 months of storage. All the other parameters studied remain acceptable but as the active chlorine content decreases, the alkalinity decreases, too, and content of the relevant impurity sodium chlorate increases. The relevance of the levels of sodium chlorate is discussed in more detail in confidential Annex 3.6.
The content of active chlorine in Super is [redacted]. Therefore, efficacy studies (EN1276 and EN1650, under use conditions) were performed on 9 month old batches. These studies confirmed efficacy of aged product at the dosage claim of 1.75% v/v Super (see 2.2.5 for Efficacy).
All the packaging types of the product are made of HDPE (volume range 5-1000 L) with a screw cap and with UN certification for compatibility for use with chemicals class 8, packaging class III and therefore the results of the stability studies can be extrapolated to all of the packagings. The packagings are suitable for the product. The product should be stored protected from frost and at temperatures equal to or below 30°C.

2.2.4 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	/	/	Sodium hypochlorite is not explosive (CAR, amended 2018). All the other components of the product do not contain functional groups associated with explosive properties. Therefore, Super can be considered as not explosive.	/
Flammable gases	/	/	Not relevant, product is a liquid.	/
Flammable aerosols	/	/	Not relevant, product is a liquid.	/
Oxidising gases	/	/	Not relevant, product is a liquid.	/
Gases under pressure	/	/	Not relevant, product is a liquid.	/
Flammable liquids	EC Method A.9	Undiluted product	No flash point below the boiling temperature. Not flammable.	Super: Determination of Flash Point, Report YT12QM, S.P. Tremain, 2017
Flammable solids	/	/	Not relevant, product is a liquid.	/
Self-reactive substances and mixtures	/	/	Super is not explosive and there are no functional groups assigned to self-reactive properties in	/

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			the compounds of the product.	
Pyrophoric liquids	/	/	Experience in manufacture and handling shows that the substance or mixture does not ignite spontaneously on coming into contact with air at normal temperatures.	/
Pyrophoric solids	/	/	Not relevant, product is a liquid.	/
Self-heating substances and mixtures	/	/	Liquids are not classified as self-heating unless they are adsorbed on a large surface.	/
Substances and mixtures which in contact with water emit flammable gases	/	/	The product is a water based formulation. Experience in production and handling shows that the product does not emit flammable gases in contact with water.	/
Oxidising liquids	/	/	Eventhough the active substance of Super has an oxidising mode of action, its concentration in the aqueous product is low (<20% w/w) and is not classified as oxidising liquid. Other components of	/

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			the product have oxygen only bound to carbon or hydrogen or are not classified as oxidising.	
Oxidising solids	/	/	Not relevant, product is a liquid.	/
Organic peroxides	/	/	Product does not contain organic peroxides.	/
Corrosive to metals	Test method PartIII sub-section 37.4 of UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria	Undiluted product	Mass loss (%) Carbon steel vapour: 0.93 50/50 vapour/liquid: 0.16 liquid: 0.04 Aluminium vapour: 2.87 50/50 vapour/liquid 70.4 liquid: 99.99 Super is corrosive to metals	Corrosion testing CLP Super F102, Report 12/001k, B. Verstraeten, 2012
Auto-ignition temperatures of products (liquids and gases)	/	/	Not required for liquids non-flammable in air.	/
Relative self-ignition temperature for solids	/	/	Not relevant, product is a liquid.	/
Dust explosion hazard	/	/	Not relevant, product is a liquid.	/

Conclusion on the physical hazards and respective characteristics of the product
The physical hazards of the biocidal product Super have been evaluated sufficiently. The product is not explosive, flammable nor oxidising. However, the product is classified as corrosive to metals.

2.2.5 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD %		
Active chlorine	Titration	50-200% of nominal available chlorine in Super n=7	R^2 = 0.9994 slope 10.495 intercept 0.1687	Reagent blank and placebo product: no reaction	100.5 – 102.5	101.2	1.09	Determination of active substance in product; LOQ not required	Validation of Titration Method WM004: Determination of Available Chlorine in Super by Titration, R. Hoppe, 2018
Chlorate ClO_3^-; measured as sodium chlorate $NaClO_3$	Ionic chromatography with conductivity detection	LOQ and 100% of experimental content of sodium chlorate in Super 2 concentration levels, 5-6 replicates per concentration	R^2 = 0.9973 Slope 26.2994 Intercept 0.00284 Range 0.068-0.478 % (w/w); LOQ to 233 % of experimental content of sodium chlorate in Super. 6 concentration levels	No interferences	At LOQ:110.3-123.8 At 100 %: 102.9-124.9	112.4 At LOQ: 113.9 At 100 %: 110.9	At LOQ: 4.3 At 100 %: 7.2	LOQ: 0.068% w/w with respect to the test sample	Validation of an IC method for the quantification of the sodium chlorate content in the test item “Super” – S-2017-03467; M.G. Guiso, 2017

Conclusion on the methods for detection and identificationof the product
The analytical method for the analysis of the product: A full validation for the quantification of sodium hypochlorite (as active chlorine) content in the product Super has been performed. The method used is the titrimetric method also described in the active substance dossier as an appropriate method to measure sodium hypochlorite in aqueous solutions. Within a sample weight of 0.3 – 1.2 g of Super, the method provides adequate specificity, linearity, precision, accuracy and robustness. For the quantification of the relevant impurity sodium chlorate in Super, an Ionic Chromatography method has been validated. The described method proved to be specific, linear, accurate and precise and was succesfully validated on Super. The analytical methods for monitoring purposes of sodium hypochlorite are adequately covered in the active substance dossier (access via LoA). Furthermore, according to the Assessment report of the Active substance "Active chlorine released from sodium hypochlorite" for PT 4, following analytical methods for residues are not required for the active substance (HClO/ClO-): -Residues in soil: Not required. Only indirect exposure. In the event of contamination of soil, e.g. due to direct application of chlorinated water, hypochlorous acid/hypochlorite anion would react rapidly with organic matter in soil. -Residues in surface water: Not required. Environmental exposure is expected via the facility drain into the STP, but rapid degradation occurs with organic matter therein. Rapid degradation occurs also with the organic matter in surface water (DT50surface water = 56 min at environmental temperature). -Residues in body fluids and tissues: Not required. Hypochlorous acid/ hypochlorite anion are oxidizing agents and degrade rapidly with organic matter. Besides, due to corrosive properties, systemic toxicity would be secondary to local effects. -Residues in food and feed: Active chlorine degrades rapidly in contact with food matrices, hence the request for analytical methods for their residues in food/feeding stuff cannot be met, but for chlorate only. This is covered by the LoA to the Active substance dossier. Furthermore, the intended use for our product Super, disinfection of milking machines and cooling tanks by CIP does not lead to the exposure of drinking water. Also no exposure to air is expected from this use. In case of an accidental release of chlorine, two analytical methods for the monitoring of chlorine in workplace air are available in the active substance dossier, which allow the determination of chlorine in workplace air in the range 0.3-7.0 mg Cl_2/m^3. In principle, the range can be expanded. Though not validated, the two available methods are published methods, so they can still be concluded to be acceptable for the purpose (determination of chlorine in workplace air).

2.2.6 Efficacy against target organisms

2.2.6.1 Function and field of use

PT04 – Food and feed area (Disinfectants)

Super is used for the disinfection by “cleaning in place with circulation“ of milking machines and milk cooling tanks.

The product is used by professional users only.

2.2.6.2 Organisms to be controlled and products, organisms or objects to be protected

The organisms to be controlled are bacteria and yeasts.
The organisms to be protected are man. The aim is to control spread of infectious diseases and to avoid contamination.

2.2.6.3 Effects on target organisms, including unacceptable suffering

The active substance active chlorine released from sodium hypochlorite exerts toxic (bactericidal and yeasticidal) effects on target organisms.

2.2.6.4 Mode of action, including time delay

Sodium hypochlorite belongs to the Chlorine-Releasing Agents (CRAs). Despite being widely studied, the actual mechanism of action of CRAs is not fully known. CRAs are highly active oxidizing agents and thereby destroy the cellular activity of proteins; potentiation of oxidation may occur at low pH, where the activity of CRAs is maximal, although increased penetration of outer cell layers may be achieved with CRAs in the unionized state. Deleterious effects of CRAs on bacterial DNA that involve the formation of chlorinated derivatives of nucleotide bases have been described.
Time delay: Active chlorine released from sodium hypochlorite is fast acting. The contact time and the concentration depend on the organisms to be controlled, the pH, the temperature and the growth media.

2.2.6.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	Field of use envisaged	Test substance	Test organism (s)	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Bactericidal	Use 1: Disinfection of milk tanks/milking machines by CIP	Super (TOM)	*S. aureus; P. aeruginosa; E. hirae; E. coli*	EN1276 Chemical disinfectants and antiseptics - Quantitative suspension test for the	Dilution rates: 1.25 – 1.00 – 0.75 – 0.50 % (in hard water) Interfering substance: 1.0% skim milk	The test item Super is bactericidal at the concentration of 1.00%.	Suspension bactericidal effectiveness with skim milk solution as interfering substance

				evaluation of bactericidal activity of chemical disinfectants for use in food, industrial, domestic and institutional areas - Test method and requirement (Phase 2 step 1)	Temperature: 40°C Contact time: 10 min		on Super (Formulation 102); S-2016-01281 AM, C. Carloni, 2016
Bactericidal	Use 1: Disinfection of milk tanks/milking machines by CIP	Super (9mo)	*S. aureus; P. aeruginosa; E. hirae; E. coli*	EN1276 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants for use in food, industrial, domestic and institutional areas - Test method and requirement (Phase 2 step 1)	Dilution rates: 2.25 – 2.00 – 1.75 – 1.50 % (in hard water) Interfering substance: 1.0% skim milk Temperature: 40°C Contact time: 10 min	The test item Super is bactericidal at the concentration of 1.75%.	Suspension bactericidal effectiveness with skim milk solution as interfering substance on Super (Formulation 102); S-2016-04741 AM, C. Carloni, 2017
Yeasticidal	Use 1: Disinfection of milk tanks/milking machines by CIP	Super (TOM)	*C. albicans*	EN1650: Chemical disinfectants and antiseptics - Quantitative suspensio	Dilution rates: 1.00 – 0.75 – 0.50 – 0.10 % (in hard water) Interfering substance:	The test item Super is yeasticidal at the concentration of 0.50%.	Suspension yeasticidal effectiveness with skim milk solution as interfering

				n test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic, and institutional areas - Test method and requirements (Phase 2, step 1)	1.0% skim milk Temperature: 40°C Contact time: 10 min		substance on Super (Formulation 102); S-2016-01282 AM, C. Carloni, 2016
Yeasticidal	Use 1: Disinfection of milk tanks/milking machines by CIP	Super (9mo)	*C. albicans*	EN1650: Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic, and institutional areas - Test method and requirements (Phase 2, step 1)	Dilution rates: 2.00 – 1.75 – 1.50 – 1.25 % (in hard water) Interfering substance: 1.0% skim milk Temperature: 40°C Contact time: 10 min	The test item Super is yeasticidal at the concentration of 1.50%.	Suspension yeasticidal effectiveness with skim milk solution as interfering substance on Super (Formulation 102); S-2016-04742 AM, C. Carloni, 2017

Conclusion on the efficacy of the product
Use 1: Disinfection of milk tanks or milking machines by CIP with circulation (PT04) This intended use with application method cleaning in place by circulation only requires phase 2 step 1 test results according to the 'Guidance on the BPR - Volume II Efficacy - Assessment and evaluation'. Disinfection has to be done after a pre-rinse of the milking installations and cooling tanks with warm water to remove all milk residues. Therefore, the *in vitro* bactericidal activity (against *P. aeruginosa, S. aureus, E. hirae* and *E. coli*) according to EN1276 and yeasticidal activity (against *C. albicans*) according to EN1650 of Super has been evaluated under the following conditions: 1.0% skim milk, 10 min contact time, 40°C, as per use instructions. Additionally, given the known decreasing content of active chlorine released from sodium hypochlorite, the product was tested both at time of manufacture (TOM) and at end of shelf life (9mo). Under these conditions Super has been demonstrated to be both bactericidal and yeasticidal at the concentration of 1.00% at time of manufacture and 1.75% at end of shelf life. The dosage of 1.75% (v/v) is therefore recommended on the label for Use 1 with efficacy against bacteria and yeast.

2.2.6.6 Occurrence of resistance and resistance management

Since the mode of action of hypochlorite is unspecific with multiple molecular sites of attack, it is very unlikely that resistance can develop.
Even though chlorine-releasing agents have been widely used during decades, only few reports on chlorine resistance could be found. A few older reports on chlorine resistance in different species such as *Legionella pneumophila* (Kuchta et al, 1985), *Methylobacterium* (Hiraishi et al, 1995) could be found. A more recent study showed that the existing diversity of bacterial isolates from drinking water has an influence on resistance of biofilms to disinfection by sodium hypochlorite (Simoes et al, 2010). A study on biocide use in the food industry and the disinfectant resistance of persistent strains of *Listeria monocytogenes* and *Escherichia coli* demonstrated that conditions are likely to be present in food factories that may give rise to the development of persistent *L. monocytogenes* and *E. coli* strains. The nature of this persistence, however, is not thought to be due to disinfectant resistance but may be due to the physiological adaptation (surface attachment, biofilm formation, reduced growth rate, quiescence) to the whole range of environmental conditions typical in chilled food factory environments (low temperature, wide pH range, fluctuating nutrient supply and moisture levels, frequency of cleaning and disinfection etc.) (Holah et al, 2002).
Overall, it can be concluded that, as the reports on chlorine resistance are so limited, resistance to chlorine, originated from a sodium hypochlorite containing disinfecting product, is highly unlikely.

References:

J. M. Kuchta, S.J., States et al, Appl Environ Microbiol. 1985 ; 50(1) : 21-26 : Enhanced chlorine resistance of tap water-adapted Legionella pneumophila as compared with agar medium-passaged strains.
A. Hiraishi, K. Furuhata et al, Appl Environ Microbiol. 1995 ; 61(6) : 2099-107 : Phenotypic and genetic diversity of chlorine-resistant Methylobacterium strains isolated from various environments.
L.C. Simoes, M Simoes et al, Appl Environ Microbiol. 2010 ; 76(19) : 6673-9 : Influence of the diversity of bacterial isolates from drinking water on resistance of biofilms to disinfection.

J.T. Holah, J.H. Taylor et al Symp Ser Soc Appl Microbiol. 2002;(31):111S-120S: Biocide use in the food industry and the disinfectant resistance of persistant strains of Listeria monocytogenes and Escherichia coli

2.2.6.7 Known limitations

No known limitations.

2.2.6.8 Evaluation of the label claims

Bactericidal and yeasticidal efficacy data have been provided to support the label claim with regards to dosage, temperature, soiling and contact time.

2.2.6.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

This product is not intended to be used in combination with other biocidal products.

2.2.7 Risk assessment for human health

2.2.7.1 Assessment of effects on Human Health

Skin corrosion and irritation

Summary table of animal studies on skin corrosion /irritation					
Method, Guideline, GLP status, Reliability	Species, Strain, Sex, No/group	Test substance, Vehicle, Dose levels, Duration of exposure	Results *Average score (24, 48, 72h)/ observations and time point of onset, reversibility; other adverse local / systemic effects, histopathological findings*	Remarks *(e.g. major deviations)*	Reference
OECD404, GLP, reliable without restriction	3 female New Zealand rabbits	The test item Super (0.5mL), was applied undiluted, to undamaged skin under semiocclusive dressing for 4 hrs.	After one hour, severe erythema and a moderate to severe oedema was noted, which was totally reversible between Day 1 and Day 7. Tissue necrosis through the epidermis (1/3) and the dermis (2/3) (noticed as scab formation) was also recorded. This scab was registered until the last day of the test (Day 7 or Day 14). For ethical reasons, the animals were euthanized on Day 14 (the first animal) and Day 7 (the two additional animals).	n/a	[redacted]

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Corrosive to the skin
Justification for the value/conclusion	An *in vivo* skin corrosion/irritation study according to OECD guidelines 404 was performed on Super. The test item applied to the healthy skin of rabbits caused tissue necrosis through the epidermis (1/3) and the dermis (2/3) after an exposure of 4 hours. In accordance with the Regulation EC No. 1272/2008, the test item must therefore be classified in Category 1C "Corrosive". The signal word "Danger" and hazard statement H314 "Causes severe skin burns and eye damage" are required.
Classification of the product according to CLP	Skin Corr. 1C; H314

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Corrosive to the eyes
Justification for the value/conclusion	No studies on eye irritation is available for biocidal product. Super has a pH > 11.5 and according to OECD 404 needs to be classified in Category 1C "Corrosive". As a result, according to Regulation EC No. 1272/2008, the product should be classified as Eye Damage 1 as well.
Classification of the product according to CLP	Eye Dam. 1; H318

Data waiving	
Information requirement	Eye irritation study (IUCLID 8.1.2)
Justification	Study scientifically not necessary / other information available. The study does not need to be conducted because the available information indicates that the criteria are met for classification as corrosive to the skin (OECD 404 test results). In addition Super is a strong base (pH>11.5).

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Corrosive to the respiratory tract.
Justification for the conclusion	No studies on respiratory tract irritation is available for Super. None of the ingredients in Super are classified for Specific target organ toxicity – Single exposure Cat 3 for respiratory tract irritation (H335). Therefore the product does not need to be classified as STOT SE3 (H335) (according to EC1272/2008).
Classification of the product according to CLP	No classification

Data waiving	
Information requirement	Respiratory tract irritation
Justification	There are sufficient data on the individual ingredients to adequately characterise the hazards of the mixture.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not a skin sensitiser
Justification for the value/conclusion	No studies on skin sensitisation is available for Super. None of the components in Super is classified for skin sensitisation Category 1 (H317).
Classification of the product according to CLP	No classification

Data waiving	
Information requirement	Skin sensitisation (IUCLID 8.3.1)
Justification	Study scientifically not necessary / other information available. There are sufficient data on the individual ingredients to adequately characterise the hazards of the mixture. Also, the study does not need to be conducted because Super is a strong base (pH>11.5).

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not considered to be a respiratory sensitiser
Justification for the value/conclusion	No studies on respiratory sensitisation is available for Super. None of the components in Super is classified for respiratory sensitisation Category 1 (H334).
Classification of the product according to CLP	No classification

Data waiving	
Information requirement	Respiratory sensitisation (IUCLID 8.3.2)
Justification	Study scientifically not necessary / other information available. There are sufficien data on the individual ingredients to adequately characterise the hazards of the mixture. The study does not need to be conducted because Super is a strong base (pH>11.5).

Acute toxicity

Acute toxicity by oral route

Summary table of animal studies on acute oral toxicity						
Method Guideline GLP status, Reliability	Species, Strain, Sex, No/group	Test substance Dose levelsType of administration *(gavage, in diet, other)*	Signs of toxicity *(nature, onset, duration, severity, reversibility)*	Value LD50	Remarks *(e.g. major deviations)*	Reference
OECD 423, GLP, reliable without restricion	Rat, Sprague Dawley, female, 3/group 1, 6/ group 2	Super ; Dose: First step: 2000 mg/kg; Second and third step: 300 mg/kg	Dose 2000 mg/kg: 2 animals deaths (one 71h and 15min post-dose and one on Day 8). The mortalities were preceded by decrease in spontaneous activity and in righting reflex, a noisy respiration and piloerection. The surviving animal showed a decrease in spontaneous activity and in righting reflex, but recovered a normal behaviour on Day 7. Dose 300 mg/kg: no mortality. No clinical signs related to the administration of the test item were observed.	>300 - <2000 mg/kg	n/a	[redacted]

Value used in the Risk Assessment – Acute oral toxicity	
Value	Toxic *via* the oral route – Category 4; LD50 >300 - <2000 mg/kg body weight
Justification for the selected value	The LD50 of Super is >300 - <2000 mg/kg body weight by oral route in the rat. In accordance with the Regulation EC No. 1272/2008 on classification, labelling and packaging of substances and mixtures, the tested product must be classified in category 4. The signal word “Warning” and hazard statement H302 “Harmful if swallowed” are required.
Classification of the product according to CLP	Acute Tox. 4; (oral) (H302)

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value/Conclusion	Not acutely toxic *via* inhalation route
Justification for the selected value	No studies on acute inhalation toxicity is available for Super. None of the ingredients of Super are classified for inhalation toxicity. According to Regulation EC 1272/2008, Super does not need to be classified for inhalation toxicity.
Classification of the product according to CLP	No classification

Data waiving	
Information requirement	Acute inhalation toxicity (IUCLID 8.5.2)
Justification	Study scientifically not necessary/ other information available. There are sufficien data on the individual ingredients to adequately characterise the hazards of the mixture.

Acute toxicity by dermal route

Summary table of animal studies on acute dermal toxicity						
Method, Guideline, GLP status, Reliability	Species, strain, Sex, No/group	Test substance, Vehicle, Dose levels, Surface area	Signs of toxicity *(nature, onset, duration, severity, reversibility)*	LD50	Remarks *(e.g. major deviations)*	Reference
OECD 402, GLP, reliable without restriction	Rat; Sprague-Dawley; male/female 5 animals per sex (one dose).	Super; undiluted; one dose of 2000 mg/kg body weight; Surface area: at least 10% of the total body surface area.	No systemic clinical signs related to the administration of the test item were observed. A slight yellow coloration was noted in all males at 24h after the test item application and was totally reversible on day 9. Erythema was noted on the treated area of all females at 24h after the test item application, turned into dryness from Day 5, into scab from Day 10 and was still noted on the last day of test in two females.	>2000 mg/kg body weight	n/a	[redacted]

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not acutely toxic *via* dermal rotue: LD50>2000 mg/kg body weight
Justification for the selected value	The LD50 of Super is higher than 2000 mg/kg body weight by dermal route in the rat. In accordance with the Regulation EC No. 1272/2008 on classification, labelling and packaging of substances and mixtures, the product must not be classified.
Classification of the product according to CLP	No classification

Information on dermal absorption

Value used in the Risk Assessment – dermal absorption	
Value	Value not needed.
Justification for the selected value	Due to the absence of clear systemic effects, derivation of dermal absorption value is not necessary.

Data waiving	
Information requirement	Dermal absorption (IUCLID 8.6).
Justification	Data is not required for human health risk assessment, as only local effects are to be considered for dermal exposure to Super. In case such assessment would become a requirement default value will be used (100 %).

Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)

Sodium hydroxide is a substance of concern contributing to the classification of Super as Skin Corr 1C. According to the "Banding evaluation scheme for classified SoCs leading to the classification of the biocidal product" a Qualitative exposure and risk assessment is required to determine whether P-statements normally associated with concerned H statements are sufficient or whether other risk mitigation measures should be applied.
Due to the H314, following P phrase is assigned: P280 - Wear protective gloves/protective clothing/eye protection/face protection, which should be sufficient to avoid skin contact when handling the concentrate. In addition following P phrases are assigned to advice the user what to do in case of accidental eye contact: P305+P351+P338+P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.
As appropriate PPEs (gloves, eye protection and coveralls) are prescribed when handling undiluted product, no adverse effects are expected from the exposure to the SoC. Further risk assessment for the SoC was not considered necessary.

Available toxicological data relating to a mixture

Available toxicological data relating to a mixture that a substance(s) of concern is a component of: not applicable.

Other

Sodium hypochlorite is a highly reactive substance which reacts immediately with organic matter at the site of first contact. However chlorate residues may still be relevant as chlorate is considered a stable metabolite (BPC APCP-WGII-2016). Therefore, secondary dietary exposure of general public to chlorate residues is possible.

The label/SPC of Super clearly states that the treated surfaces need to be rinsed with water after the treatment, which is considered to be an efficient measure to reduce possible residues to end up in the milk. To prove this, field trials have been performed with the product and milk samples have been analysed for the presence of chlorate. The results of these studies are summarized in the Dietary Exposure section.

2.2.7.2 Exposure assessment

Professional users need to make an in-use dilution (1.75% v/v product) in hot water. After dilution the formulation is applied by Cleaning-In-Place (CIP). Therefore, the farmer (end user) can be dermally and respiratory exposed to chlorine species during the mixing and loading. After application of Super, the milk installations, pipelines and tanks are always rinsed with clean water before the next use, to remove potential residues.
As Super is intended for professional use only, oral exposure is considered negligible.
Sodium hypochlorite does not exist as a pure substance, but only in the form of aqueous solutions. When diluted in water, sodium hypochlorite is partly transformed into hypochloric acid (HOCl), depending on the pH of the solution. Under acidic conditions, hypochloric acid can decompose with the liberation of free chlorine:
$HOCl + H+ + Cl- \leftrightarrow Cl_2 + H_2O$
According to the CAR at the alkaline pH, which is the case for undiluted Super (>pH 11.7 for 1% solution), equilibrium is shifted to OCl- and no chlorine gas is formed. Only a small amount of hypochloric acid will be combined with organic matter present on surface and the amount of chlorine evaporating into the ambient air is considered negligible. However, upper airway exposure to aerosol during mixing and loading cannot be excluded and therefore the associated risk needs to be considered.

Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product

Summary table: relevant paths of human exposure							
Exposure path	Primary (direct) exposure			Secondary (indirect) exposure			
	Industrial use	Professional use	Non-professional use	Industrial use	Professional use	General public	Via food
Inhalation	n.a	yes	n.a	n.a	no	no	no
Dermal	n.a	yes	n.a	n.a	no	no	no
Oral	n.a	no	n.a	n.a	no	no	yes

List of scenarios

Super is used only by disinfection of milking systems/tanks by Cleaning-In-Place (CIP). This specific use is also addressed in the assessment report of the active substance, with an acceptable outcome for a product containing 14% active chlorine, when Super contains 4%. Professional users can make an in-use dilution in hot water manually or couple the containers to an automated dosing system. The formulation is applied then by CIP with circulation. During the mixing and loading operation, the professional users (end user) can be dermally and respiratory exposed to chlorine species contained in the undiluted formulation. The exposure during manual mixing and loading (Scenario 2) is considered to be the worst case. Exposure during application and post-application (handling of empty barrels) phase are considered not relevant/negligible.
In the assessment report for the active substance, two additional scenarios were included for maintenance (repair of broken circuit or reservoir). Although these are sporadic events and both scenarios had an acceptable outcome in the assessment report for a product containing 14% active chlorine, scenario was included here for transparency.

Summary table: scenarios			
Scenario number	Scenario (e.g. mixing/ loading)	Primary or secondary exposure Description of scenario	Exposed group (e.g. professionals, non-professionals, bystanders)
1.	Mixing and loading (automated dosing)	Primary exposure - Coupling of the containers to an automated dosing system	professionals
2.	Mixing and loading (manual dosing)	Primary exposure - Manually prepare an in-use dilution in hot water	professionals
3.	Post application - maintenance	Primary exposure – Maintenance (repair of broken circuit or broken pipeline/stock tank)	professionals

Industrial exposure

Not applicable, no industrial exposure is foreseen.

Professional exposure

As Super is only intended for professional use, primary oral exposure is considered to be negligible. The main routes of primary exposure are dermal and inhalation. As for sodium hypochlorite, systemic effects are considered to be secondary to local effects, the risk assessment will be performed based on local effects. For local dermal effects, a qualitative risk assessment was performed. For local respiratory effects a semi-quantitative risk assessment was made calculating external inhalation exposure.
At pH values over 10, the hypochlorite anion (OCl-) is the predominant species and only exposure to aerosols of NaOCl (as available chlorine) is considered relevant. The minute fraction of volatile hypochlorous acid (HOCl) is considered negligible (NaOCl CAR 2017).

Biocide product contains one substance of concern, sodium hydroxide. The vapour pressure of it is below 10^{-5} Pa at 25 ºC so it is only slightly volatile. Inhalation exposure to vapour is therefore considered negligible. Inhalation exposure to aerosols is assessed when relevant, As the concentrate is classified as Skin Corr 1C (H314), dermal exposure during the mixing and loading and maintenance phases (Scenarios 1, 2 or 3 below) is controlled by using protective gloves, coveralls and eye protection.
As the diluted formulation is applied by CIP only, no exposure of the professional users are expected during disinfection or post-application phase.

Scenario [1] Mixing and loading in case of automated dosing = Coupling of the containers

Description of Scenario [1]		
Loading: Coupling of the containers to an automated dosing system without direct handling and in closed system. Task duration: 1 min/day, Frequency: 50x/year (estimated). Concentration of active chlorine released by sodium hypochlorite (concentrate): 4.0% w/w. According to HEEG opinion 1 (2008), the exposure during connecting lines would be very low or accidental and as a consequence can be considered negligible compared to other related tasks.		
	Parameters	Value
Tier 1	n/a	

Scenario [2] Mixing and loading in case of manual dosing

Description of Scenario [2a] – active substance		
Mixing & Loading: The in-use solution is prepared manually by pouring concentrate product in hot water when exposure via dermal and inhalation route can occur. For inhalation exposure assessment, the Mixing & Loading model 7 for pouring liquid (HEEG opinion 1 (2008)) was used. Task duration: 10 min/event (default) Local dermal exposure was assessed qualitatively. Concentration of active chlorine released by sodium hypochlorite (concentrate): 4.0% w/w.		
	Parameters	Value
Tier 1	Indicative inhalation exposure	0.94 mg/m^3
	Active chlorine conc	4.0%
Description of Scenario [2b] – substance of concern: sodium hydroxide		
Mixing & Loading: Inhalation exposure to sodium hydroxide when pouring the product to warm water is assessed using the Mixing and loading model 7 (HEEG opinion 1, 2008). Task duration: 10 min/event (default) Local dermal exposure was assessed qualitatively. Concentration of sodium hydroxide: 10 % w/w.		
	Parameters	Value
	Indicative inhalation exposure	0.94 mg/m^3
	sodium hydroxide	10.0%

Scenario [3] Maintenance – repair of broken circuit or broken stock tank/pump

Description of Scenario [3a] – active substance		
Maintenance: Dermal and inhalation exposure can occur during maintenance of the processing circuit (contact to the in-use dilution) and during maintenance of the pipeline/stock tank (contact to the concentrated product). For inhalation exposure assessment, the Mixing & Loading model 7 for pouring liquid (HEEG opinion 1 (2008)) was used. Task duration: 1 hour. Local dermal exposure was assessed qualitatively. Concentration of active chlorine released by sodium hypochlorite (concentrate): 4.0% w/w and in-use dilution 1.75% v/v.		
	Parameters	Value
Tier 1	Indicative inhalation exposure	0.94 mg/m^3
	Active chlorine concentrate	4.0%
	Active chlorine in-use dilution	1.75%

Description of Scenario [3b] – substance of concern: sodium hydoxide		
Maintenance: Inhalation exposure to sodium hydroxide was assessed with the Mixing & Loading model 7 for pouring liquid (HEEG opinion 1 (2008)). Task duration: 1 hour. Local dermal exposure was assessed qualitatively. Concentration of sodium hydroxide: 10 % w/w (worst-case contact to concentrate).		
	Parameters	Value
Tier 1	Indicative inhalation exposure	0.94 mg/m^3
	Sodium hydroxide concentration	10.0%

Calculations for Scenario [1-3]

Summary table: estimated exposure from professional uses – active substance			
Exposure scenario	Tier/PPE	Local Dermal exposure [concentration %]	Local inhalation exposure [total a.s. mg avCl/m^3]
Scenario [1]	Tier 1/No PPE	no exposure	no exposure
Scenario [2a]	Tier 1/ no RPE*	4.0	0.0376
Scenario [3a]	Tier 1/ no RPE*	4.0	0.0376

*Gloves, coverall and eye protection used during mixing and loading phase or maintenance.

Summary table: estimated exposure from professional uses – substance of concern			
Exposure scenario	Tier/PPE	Local Dermal exposure [concentration %]	Local inhalation exposure [mg/m^3]
Scenario [2b]	Tier 1/ no RPE*	10.0	0.094
Scenario [3b]	Tier 1/ no RPE*	10.0	0.094

* Gloves, coverall and eye protection used during mixing and loading phase or maintenance.

Further information and considerations on scenario [1-3]
Use of gloves, coveralls, eye protection (P280) are mandatory when handling the concentrate, triggered by the classification of Super (Skin Corr. 1C). Also, the active chlorine concentration in the concentrate is 4.0% w/w, which is higher than the dermal NOAEC value of 1% av chlorine, which triggers the need for skin protection. Therefore, the use of gloves, suitable protective clothing and eye protection should be prescribed for the professional user for mixing and loading step. The advised gloves, long sleeved clothing and boots on the MSDS provide adequate protection (90% for protective gloves for challenges by a liquid, according to HEEG opinion 9) against the concentrated solution (consentration with gloves 0.4 %< NOAEC).

Combined scenarios

Not applicable, a combined exposure assessment, in case the same user is exposed during the different consecutive tasks, is only relevant in order to assess systemic risks. For Super, only local effects are relevant. Also, the same professional user is only exposed during mixing and loading of the product. Scenario 2 represents the worst-case, in case of manual instead of automated dosing.

Secondary exposure

Bystanders/non-users are not assumed to be present during the application of the product. Secondary exposure of bystanders/non-users upon dermal contact with treated surfaces is also considered to be non-relevant since only inner surfaces are treated by CIP.

Non-professional exposure

Not applicable, no non-professional exposure is foreseen.

Exposure of the general public

Not applicable, no exposure of the general public is foreseen.

Monitoring data

There are no monitoring data available on the product.

Dietary exposure

Currently, no agreed and published guidance is available for the estimation on dietary risk from transfer of biocidal active substances into food in the professional settings. Thus, no dietary risk assessment can be provided at this stage for the intended uses of the active chlorine releaser NaOCl in PT4. Instead, EFSA Scientific Opinion of the EFSA CONTAM Panel on 'Risk for public health related to the presence of chlorate in food' (EFSA Journal 2015; 13:4135) is used for evaluation.
EFSA Panel on Contaminants in the Food Chain (CONTAM Panel) evaluated the exposure and risk arising from chlorate residues found in food (including milk) and drinking water. Chlorate content in all food commodities assessed ranged from 3 µg/kg (alcoholic beverages) to 417 µg/kg (herbs and spices) (mean upper bound values). The mean chlorate value for drinking water was 39 µg/L (mean upper bound).
An acute and chronic exposure assessment was performed for different population groups, using consumption data from the EFSA Comprehensive Database and the measured chlorate levels. The mean and 95th percentile acute exposures were below the ARfD (36 µg chlorate/kg bw) for all age groups indicating no concern. Also, chronic exposure of adolescent and adult age classes did not exceed the TDI (3 µg chlorate/kg bw). However, at the 95th percentile, the TDI was exceeded in all surveys for infants and toddlers and in some surveys in other children, indicating that chronic exposures are of concern in particular in younger age groups with mild or moderate iodine deficiency.
Because chlorate is no longer used as pesticide, chlorate contamination in food is likely to be mainly derived from biocidal uses of chlorine and hypochlorite. CONTAM Panel assumes that chlorate residues in food result mainly from the use of chlorinated water for food processing and from the disinfection of surfaces and food processing equipment coming into contact with food.
Potential chlorate residues from the application of chlorine and hypochlorite in PT4 is considered to be included in the measured chlorate residue values, and the conclusions drawn by the EFSA CONTAM Panel on chlorate residues cover thus also the dietary risk arising from PT4 uses fo chlorine and hypochlorite. Consequently, no dietary risk assessment is deemed necessary for the intended professional uses of the active chlorine releaser NaOCl in PT4.

Super is a PT4 disinfectant, used for the disinfection of milking machines and milk cooling tanks. So for this type of use, exposure of the milk is in theory possible. Therefore, secondary dietary exposure of general public to chlorate residues is possible.

List of scenarios

Summary table of main representative dietary exposure scenarios			
Scenario number	Type of use[1]	Description of scenario	Subject of exposure[2]
4.	Professional use	Disinfection of milk tanks/milking machines by Cleaning in Place (CIP)	Milk

[1] e.g. animal husbandry, food industry, professional use, residential use.
[2] e.g. chicken, milk, beer

Information of non-biocidal use of the active substance

Not applicable since this is an application for biocidal products.
The active substance is not used in Veterinary field, Plant Protection products or as food/feed additive.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Not applicable, not applied on animals.

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)

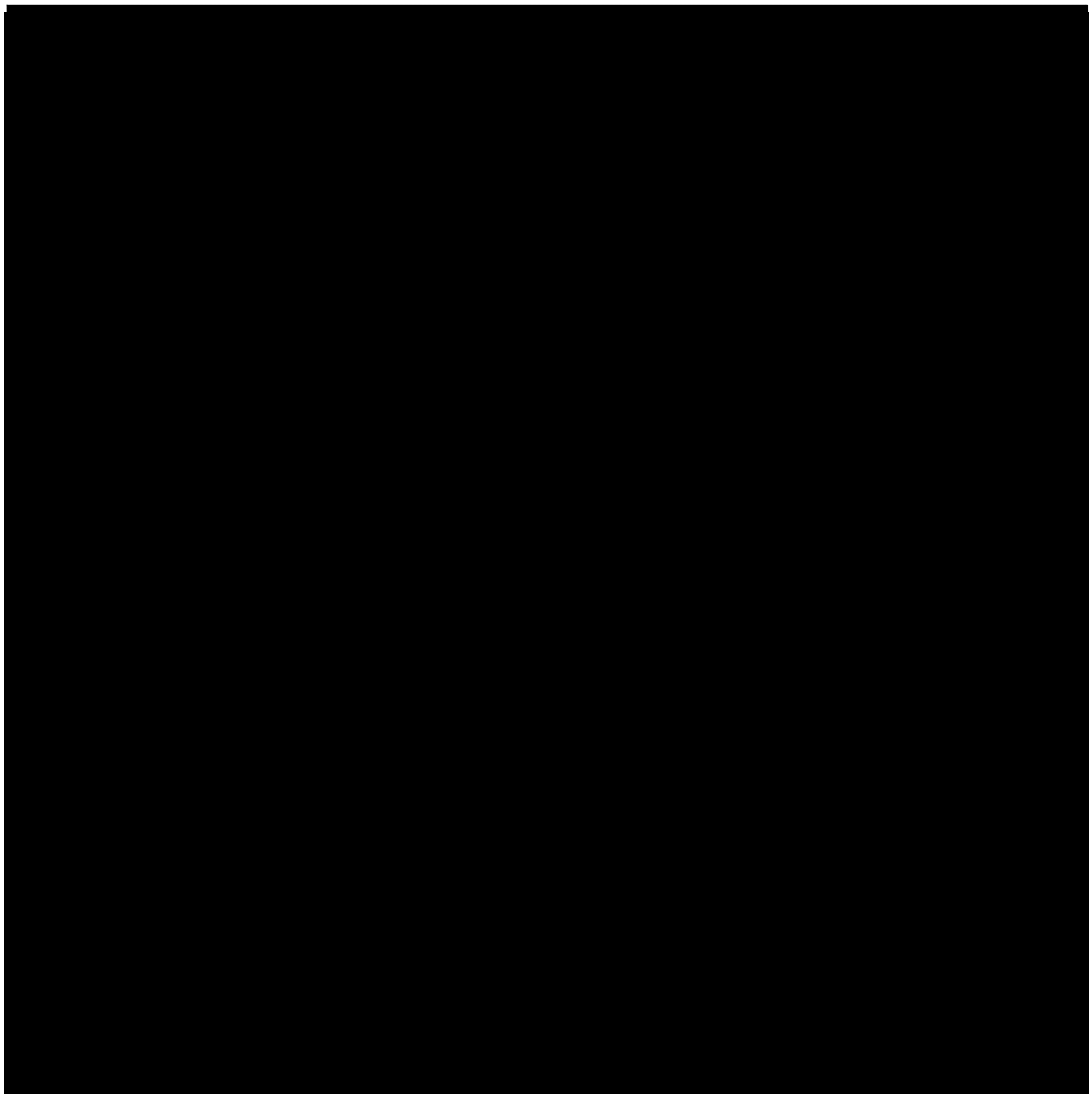
Scenario [4]
Sodium hypochlorite is a highly reactive substance which reacts immediately with organic matter at the site of first contact. However chlorate residues may still be relevant as chlorate is considered a stable metabolite (BPC APCP-WGII-2016). Therefore, secondary dietary exposure of general public to chlorate residues is possible.

The label/SPC of Super clearly states that the treated surfaces need to be rinsed with water before and after the treatment, which is considered to be an efficient measure to reduce possible residues to end up in the milk. To further investigate this, field trials have been performed on farm with Super, used in normal routine and conform label instructions. Since the active chlorine content decreases during storage, while chlorate increases, the same trial has been performed with a fresh (TOM) and aged (LOP) lot of Super. During both trials, bulk tank milk samples of three consecutive milk pick-ups (PU1, PU2 and PU3 in graphs below) have been analysed for the presence of chlorate (impurity). In addition, the residues in waste water resulting from using Super for disinfection of the milking equipment (ME) and the bulk tank (BT) were evaluated by collecting rinse water samples (including pre- and post-rinse) during the disinfection cycles before milk pick-up. As a negative control, an additional trial was performed with a chlorine free detergent [redacted].
Several laboratories specialized in residue/contaminant analysis in food and water were contacted for their ability to test for chlorate both in milk and water under GLP. No such laboratory could be identified. Therefore, tests on field trial samples were performed under the highest available accreditation, ISO 17025.

The below table lists the LOD and LOQ for the different tests:

		WATER		MILK	
	Methodology	LOD	LOQ	LOD	LOQ
Chlorate	LC-MS/MS	2 µg/L	2 µg/L	2 µg/kg	2 µg/kg

A trial report is included in Appendix 1 (confidential) of this PAR (see section 3.4). Graphs of the results for Super are included below. Next to the waste water samples (BT and ME: PRE, MAIN and POST) and the milk samples (MILK), a water sample of the water used during the trial (WATER) and a freshly diluted Super sample (FRESH) were also analysed. It has to be noted that for the trial with the aged lot, the milking equipment (ME) before the third milk pick-up (PU3) was cleaned with an acid instead of Super, so these samples were not included as not relevant (no residues detected).



As expected for chlorate, generally higher values are found for the aged lot (LOP) compared to the fresh lot (TOM). This can be ascribed to the increase in chlorate content during storage of sodium hypochlorite solutions. Chlorate was detected in all waste water samples of the disinfection solution (DISINFECT). The levels found are in agreement with the measurement of chlorate levels over shelf-life (see 2.2.2). Significant lower levels of chlorate were detected in most of the pre- and post-rinse samples (PRE/POST) indicating the importance of these steps to reduce residue transfer to milk. This is indeed confirmed by the measurements in milk, as the highest level detected was only 18 µg/kg milk. The average value for 6 milk pick-ups was 6.2 µg/kg milk.

The maximal measured chlorate concentration in bulk tank milk was 18 µg/kg milk. At WGIV 2017 it was agreed to use a daily milk consumption of 0.45 L/day for adults (EFSA PRIMo version 2, based on highest mean for Dutch populations) and 0.46 L/day for infant/toddlers (EFSA PRIMo version 2, based on highest mean for French population). The maximal daily chlorate intake for toddlers of 10 kg, resulting from the use of Super, when based on the

worst-case chlorate measurement of 18 µg/kg milk would therefore be ((18*0.46)/10 =) 0.83 µg/kg body weight. For adults the daily intake, based on this worst-case assumption would be only ((18*0.45)/60=) 0.13 µg/kg.

Conclusion

Presented field trials demonstrate that rinsing of the treated surfaces with water before and after the treatment is an efficicent measure to reduce the possible residues in milk and the transfer of residues into food (milk) is limited.

Estimating transfer of biocidal active substances into foods as a result of non-professional use

Not applicable: product is not intended for non-professional use.

Exposure associated with production, formulation and disposal of the biocidal product

Not relevant.

Aggregated exposure

Not relevant because systemic effects are not relevant for active chlorine. Only local effects should be considered and for local effects, combining exposure estimates from the different uses is not relevant.

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	Exposed group (e.g. professionals, non-professionals, bystanders)	Tier/PPE	Estimated total uptake
1	Professionals	Tier 1/ no RPE*	n.a
2a	Professionals	Tier 1/ no RPE*	0.0376 mg avCl/m^3
2b	Professionals	Tier 1/ no RPE*	0.094 mg NaOH/m^3
3a	Professionals	Tier 1/ no RPE*	0.0376 mg avCl/m^3
3b	Professionals	Tier 1/ no RPE*	0.094 mg NaOH/m^3

* Gloves, coverall and eye protection during mixing and loading phase or maintenance.

Risk characterisation for human health

Reference values to be used in Risk Characterisation

	Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
NaOCl	AELshort-term / medium term / long term	n/a, NaOCl does not cause systemic effects				
	$NOAEC_{dermal}$	human (dermatitis patients) 48 h-patch test study	/	/	/	1% available chlorine
NaOCl and HClO	$AEC_{inhalation}$	No repeated dose inhalation toxicity study on NaOCl/HClO is available. In the absence of data, the BPC TOX-WGIII-2016 agreed to derive an $AEC_{inhalation}$ based on chlorine data: Monkey 52-wks subchronic repeated dose inhalation study human volunteer single dose inhalation study (4-8 h) human volunteer repeated dose inhalation study (3 d, 6 h/d)	1.5 mg avCl/m^3	3.2		0.5 mg avCl/m^3
Sodium hydroxide	TWA (15 min)	Occupational exposure limit in Finland				2 mg/m^3
Chlorate	ARfD	based on human 12-wks repeated dose oral (drinking water) clinical study	/	/	/	36 µg chlorate/kg bw*

		according to EFSA CONTAM Panel (EFSA Journal 2015;13(6):4135				
	ADI	Based on the TDI for perchlorate (derived from human observations) according to EFSA CONTAM Panel (EFSA Journal 2015;13(6):4135)	/	/	/	3 µg chlorate/kg bw*

[1] Assessment report on NaOCl: interspecies AF (toxicodynamics x –kinetics): 1x1, intra-species AF (toxicodynamics x –kinetics): 3.2 x 1, AF for duration: 1, AF for uncertainties: 1)

*Assessment report on NaOCl: In absence of data, the WGIII-2016 agreed on the ADI and ARfD values proposed by the EFSA panel on Contaminants in the Food Chain (EFSA Journal 2015; 13(6):4135, 103p)

Maximum residue limits or equivalent

Not relevant for substances such as NaOCl which act by a local mode of action only.

The European Commission has recently given a maximum residue levels of chlorate in food (Commission Regulation amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorate in or on certain products, June 2020). The MRL in milk and the reference value in drinking water are given in the table below.

MRLs or other relevant reference values	Reference	Relevant commodities	Value
MRL for milk	Commission Regulation 2020/749 amending Annex III to Regulation (EC) No 396/2005	chlorate	0.1 mg chlorate/kg
Drinking water limit	“Chlorite and Chlorate in Drinking-Water”, WHO (2005)	chlorate	0.7 mg chlorate/L

Risk for industrial users

Not applicable, no exposure of industrial users is foreseen.

Risk for professional users

The occupational risk assessment for the biocidal product Super takes into account local effects of the active substance active chlorine. Sodium hydroxide is identified as a substance of concern based on classification according to Annex VI of Regulation (EC) 1272/2008 with H314 (Skin Corr. 1C). The occupational risk assessment takes into account systemic and local effects of the substance of concern sodium hydroxide.

Systemic effects

Active chlorine has no systemic effects. It acts by a local mode of action only. Thus, only local effects should be considered.

Combined scenarios
Not applicable, no combined exposure is foreseen.

Local effects

For local respiratory effects a semi-quantitative risk assessment was made based on the AEC inhalation for active chlorine, and the derived external inhalation exposures for this substance during the different scenarios. For local dermal effects, a qualitative risk assessment was performed.

A semi-quantitative risk assessment for exposure via inhalation is presented below.

Task/ Scenario	Tier	$AEC_{inhalation}$ (mg avCL/m^3)	Estimated uptake (mg avCl/m^3)	Estimated exposure/ AEC (%)	Acceptable (yes/no)
1	1, no RPE	0.5	no exposure	no exposure	Yes
2a	1, no RPE		0.0376	8	Yes
3a	1, no RPE		0.0376	8	Yes

Local respiratory effects are not expected (Estimated external exposure < $AEC_{inhalation}$) for any of the exposure scenarios.

The primary toxic effect of the substance of concern sodium hydroxide is skin corrosion. The quantitative risk characterisation for professional users takes into account inhalation exposure to sodium hydroxide resulting form use of the biocidal product. As reference value the TWA value (15 min) of 2 mg/m^3 is used. The risk assessment result for inhalation route referring to the substance of concern sodium hydroxide in the biocidal product Super is given in the table below. The scenario 2b (manual loading of the product) is a worst case scenario and covers also scenarios 1 and 3.

Scenario	Inhalation exposure NaOH mg/m^3	TWA-value mg/m^3	Estimated exposure/TWA (%)	Accetable
Manual pouring of product for preparing an in-use solution (scenario 2b)	0.094	2	5	yes

Local dermal effects are not expected for any of the above scenarios. A qualitative risk assessment has been performed and is summarized in the below table. Briefly, the active chlorine concentration in the concentrate is 4.0% w/w, which is higher than the dermal NOAEC value of 1% av chlorine, which triggers the need for skin protection when handling the concentrate. Use of gloves, coveralls, eye protection (P280) are mandatory when handling the concentrate, triggered by the classification of Super (Skin Corr 1C). The advised gloves on the MSDS provide adequate protection (90% for protective gloves for challenges by a liquid, according to HEEG opinion 9) against the active chlorine in the concentrated solution (concentration with gloves 0.4% < NOAEC).
As the diluted formulation is applied by CIP only, no exposure of the professional users are expected during disinfection. Therefore, the use of gloves is not required and there are no risks for local dermal effects.

Hazard			Exposure							Risk
Hazard Category	Effects in terms of C&L	Additional relevant hazard information	PT	Who is exposed	Tasks/uses/processes	Potential exposure route	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Conclusion on risk
High	Skin Corr 1C (H314)	-	4	Professional user	Scenario 1: Coupling of the containers to an automated dosing system.	Skin Eye Respiratory tract	Frequency: ±50x/year (estimate). Duration: Few minutes per event or less	Very high level of containment, practically no exposure	Personal Protective equipment: Already adviced due to the classification of Super concentrate (P280) - Hand protection: Neoprene gloves. Impermeable. Use of appropriate gloves also triggered by active chlorine concentration in the concentrate (4%) that is >NOAEC of 1% av chlorine. - Eye Protection: Safety glasses with side-shields. -Skin Protection: Clothing: Long sleeved clothing. Impermeable. Boots: Chemical resistant apron. boots General safety and hygiene measures: Keep away from food, drink and animal feedingstuffs. Do not eat, drink or smoke when using this product. Avoid contact with skin, eyes and clothing. Wear suitable gloves and eye/face protection. In case of insufficient ventilation wear suitable respiratory equipment. Contaminated work clothing should not be allowed out of the workplace. Regular cleaning of equipment, work area and clothing.	Acceptable +used for short duration +low respiratory exposure level compared to $AEC_{inhalation}$ (see semi-quantitative RC) + Professionals using PPE's
High	Skin Corr 1C (H314)	-	4	Professional user	Scenario 2: Mixing and loading (manual dosing: Preparation of the ready to-use solution (pouring liquid)	Skin Eye Respiratory tract	Frequency: 2x/day Duration: Few minutes per day or less	Controlled exposure	Personal Protective equipment: Already adviced due to the classification of Super concentrate (P280) - Hand protection: Neoprene gloves. Impermeable. Use of appropriate gloves also triggered by active chlorine concentration in the concentrate (4%) that is >NOAEC of 1% av chlorine. - Eye Protection: Safety glasses with side-shields.	Acceptable +used for short duration +low respiratory exposure level compared to $AEC_{inhalation}$ (see semi-quantitative RC) + Professionals using PPE's

									-Skin Protection: Clothing: Long sleeved clothing. Impermeable. Boots: Chemical resistant apron. boots General safety and hygiene measures: Keep away from food, drink and animal feedingstuffs. Do not eat, drink or smoke when using this product. Avoid contact with skin, eyes and clothing. Wear suitable gloves and eye/face protection. In case of insufficient ventilation wear suitable respiratory equipment. Contaminated work clothing should not be allowed out of the workplace. Regular cleaning of equipment, work area and clothing.	
High	Skin Corr 1C (H314)	-	4	Professional user	Scenario 3: Post application: Maintenance (repair of broken circuit or broken pipeline/stock tank)	Skin Eye Respiratory tract	Frequency: infrequently, 1 h at a time	Controlled exposure	Personal Protective equipment: Already adviced due to the classification of Super concentrate (P280) - Hand protection: Neoprene gloves. Impermeable. Use of appropriate gloves also triggered by active chlorine concentration in the concentrate (4%) that is >NOAEC of 1% av chlorine. - Eye Protection: Safety glasses with side-shields. -Skin Protection: Clothing: Long sleeved clothing. Impermeable. Boots: Chemical resistant apron. boots	Acceptable +exposure for short duration infrequently +low respiratory exposure level compared to $AEC_{inhalation}$ (see semi-quantitative RC) + Professionals using PPE's

Conclusion
Sodium hypochlorite is not considered to have systemic effects. Only local effects should be considered.

A semi-quantitative risk assessment has been performed for the respiratory exposure to Super. The estimated external exposure was for all scenarios well below the $AEC_{inhalation}$, indicating acceptable use of the product with regards to inhalation exposure to sodium hypochlorite. A risk assessment of the substance of concern via inhalation route was also performed. The estimated external exposure for professional users was below the short term occupational exposure value (15 min TWA) of sodium hydroxide.

A qualitative risk assessment has been performed for the dermal exposure, indicating acceptable risk for all scenarios. The active chlorine concentration in the concentrate is 4.0% w/w, which is higher than the dermal NOAEC value of 1% av chlorine, which triggers the need for skin protection when handling the concentrate. Use of gloves, coveralls, eye protection (P280) are mandatory when handling the concentrate, triggered by the classification of Super (Skin Corr 1C). The advised gloves on the MSDS provide adequate protection (90%) against the active chlorine in the concentrated solution (concentration with gloves 0.4% < NOAEC).

As the diluted formulation is applied by CIP only, no exposure of the professional users are expected during disinfection. Therefore, the use of gloves is not required and there are no risks for local dermal effects.

In conclusion, no adverse effects are expected for protected (gloves, eye-protection and suitable protective clothing) professional users from exposure to sodium hypochlorite by application of Super during mixing and loading and maintenance, and for unprotected professional users during CIP application.

Bystanders/non-users are not assumed to be present during the application of the product. Secondary exposure of bystanders/non-users upon dermal contact with treated surfaces is also considered to be non-relevant since only inner surfaces are treated by CIP.

Risk for non-professional users

Not applicable, no exposure of the non-professional user is foreseen.

Risk for the general public

Not applicable, no exposure of the general public is foreseen.

Risk for consumers via residues in food

Chlorine species are highly reactive and will rapidly degrade on surfaces (decomposition to physiological sodium and chloride) which effectively reduces the possibility of any residual concentrations. The BPC APCP-WGII-2016 concluded that chlorate residues may still be relevant as chlorate is considered a stable metabolite. Sodium chlorate is a by-product of the manufacturing process and can be formed during storage. Thus, chlorate may represent a worst-case for sodium hypochlorite residues.

The rinsing is advised in the product use instruction. The efficacy of rinsing was investigated in the field trials where the highest chlorate level in milk detected was 18 µg/kg milk. The average value for 6 milk pick-ups was 6.2 µg/kg milk. The chlorate levels found in milk after use of Super are significantly below the maximum residue limit 0.1 mg/kg milk.

For chlorate, a TDI (Tolerable Daily Intake) of 3 µg chlorate/kg body weight has recently been proposed by the European Food Standards Agency (EFSA). This is also the ADI for chlorate that has been set in the Assessment Report for the active substance “Active chlorine released from sodium hypochlorite’’. Based on the agreed daily milk consumption, the daily chlorate intake resulting from the use of Super for adults would be 0.13 µg/kg and for toddlers 0.83 µg/kg body weight, which is well below the ADI for chlorate.

Conclusion

The label/SPC of Super clearly states that the treated surfaces need to be rinsed with water before and after the treatment. Presented field trials demonstrate that this is an efficient measure to reduce possible residues to end up in the milk. Measured chlorate residues in bulk tank milk (highest level 18 µg/kg milk) was well under the MRL value for chlorate (0.1 mg/kg milk).

For chlorate, all measured values in milk lead to a daily intake for toddlers below the ADI of 3 µg/kg body weight for chlorate, with a worst case daily intake of 0.83 µg/kg body weight. Therefore, it can be concluded that the risk for consumers via residues in milk is acceptable when Super is used according to label instructions.

Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

Not relevant, only local effects. The described methodology in the guidance for the risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product is only relevant for assessment of systemic risks. For local effects of mixtures CLP rules apply. One co-formulant is identified as a substance of concern contributing to the classification of Super as Skin Corr. 1C (H314): sodium hydroxide. According to the “Banding evaluation scheme for classified SoCs leading to the classification of the biocidal product” a Qualitative exposure and risk assessment is required to determine whether P-statements normally associated with concerned H statements are sufficient or whether other risk mitigation measures should be applied. Due to the H314 phrase of Super, following P phrase is assigned: "P280 - Wear protective gloves/protective clothing/eye protection/face protection", which should be sufficient to avoid skin contact when handling the concentrate. So no adverse effects are expected from the exposure to the SoC. In addition following P phrases are assigned to advice the user what to do in case of accidental eye contact: "P305+P351+P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor."
Therefore it can be considered that the risk assessment on the active substance should cover the safety of the product.

2.2.8 Risk assessment for animal health

Not applicable. There is no risk expected for the animal. No applications on animals is foreseen.

2.2.9 Risk assessment for the environment

Super contains sodium hypochlorite (CAS 7681-52-9) releasing the active substance active chlorine. The product is formulated to contain 4% w/w active chlorine. The hypochlorous acid (HClO) is in equilibrium with hypochlorite anion (ClO-) and chlorine (Cl2). This equilibrium depends on the pH value: chlorine is available below pH 4, in the neutral pH range hypochlorous acid is the predominant species and at pH values higher than 10 (as is the case for Super), the only species present is the hypochlorite ion. Active chlorine or free available chlorine (FAC) is the sum of Cl_2, HOCl and ClO^-. This FAC is consumed by reaction with organic matter and most (about 99%) of the active chlorine is thereby converted to inorganic chloride.

2.2.9.1 Effects assessment on the environment

Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

There are no ecotoxicologically relevant non-active ingredients added to the formulation. The non-active substances are not classified regarding environment hazards based on valid information available on their material safety data sheets. In addition, there are no active substances from other PTs present in the product. Therefore, the classification of the products can be based on active substance only. So for this section we refer to the active substance dossier (via a LoA).

In the case of Super, the active substance is the only substance of concern for the environment. Super contains 4.2 % sodium hypochlorite classified as Aquatic Acute 1 (H400; M factor = 10) and Aquatic Chronic 1 (M factor = 1). Therefore, Super is classified as Aquatic Acute 1 (H400) and Aquatic Chronic 2 (H411). The labelling of the product can be adjusted to H410.

Further Ecotoxicological studies

Not applicable, no studies have been performed on Super.
The active substance is the only substance of environmental concern in the product (see above). Therefore, additional ecotoxicological studies are not required for product authorisation.

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)

Not applicable, no studies have been performed on Super. The use of sodium hypochlorite for the disinfection of milking equipment by cleaning-in-place (CIP) is described as one of the intended uses in the active substance authorisation report and effects on any other non-target organisms are therefore not assumed.

So for this section we refer to the active substance dossier (via a LoA).

Supervised trials to assess risks to non-target organisms under field conditions

Not applicable, the biocidal product is not in the form of baits or granules.

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

Not applicable, the biocidal product is not in the form of baits or granules

Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)

This requirement is not applicable since Super is used indoors in the milking parlour, above an impermeable floor.

Foreseeable routes of entry into the environment on the basis of the use envisaged

The product is mainly used indoors in the milking parlour, above an impermeable floor. There is no direct release to air, soil or surface waters. The product may enter into the environment indirectly via two different routes of disposal for wastewater from the milking parlour:

1. Via sewage to the sewage treatment plant (STP)
2. Discharge to a local wastewater treatment system

For the distribution we refer to the section “Fate and distribution in the environment” of the active substance dossier.

Further studies on fate and behaviour in the environment (ADS)

Not applicable, no studies have been performed on Super. Super is used indoors in the milking parlour, there is no direct release to air, soil or surface waters. The use of NaOCl for disinfection of milking equipment by cleaning-in-place is described as an intended use in the CAR, we therefore refer to the LoA.

Leaching behaviour (ADS)

Not applicable, data not relevant for veterinary hygiene and food and feed area disinfectants.

Testing for distribution and dissipation in soil (ADS)

Not applicable, no studies have been performed on Super. Super is used indoors in the milking parlour, there is no direct release to air, soil or surface waters. The use of NaOCl for disinfection of milking equipment by cleaning-in-place is described as an intended use in the CAR, we therefore refer to the LoA.

Testing for distribution and dissipation in water and sediment (ADS)

Not applicable, no studies have been performed on Super. We refer to the active substance dossier for available data (via LoA).

Testing for distribution and dissipation in air (ADS)

Not applicable, no studies have been performed on Super. We refer to the active substance dossier for available data (via LoA).

If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)

Not applicable, the product is used indoors.

If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

Not applicable, the product is used indoors.

2.2.9.2 Exposure assessment

General information

Assessed PT	PT 4
Assessed scenarios	Disinfection of milking machines and cooling tanks
ESD(s) used	Emission Scenario Document for Product Type 4: DISINFECTANTS USED IN FOOD AND FEED AREAS. EUR 25117 EN – 2011
Approach	Scenario 1: Average consumption
Distribution in the environment	Reference to active substance dossier
Groundwater simulation	Not applicable
Confidential Annexes	NO
Life cycle steps assessed	Production: No Formulation: No Use: Yes Service life: n/a
Remarks	

Emission estimation

Disinfection of milking installations is performed by CIP: the disinfectant is added to the circulating water and pumped through the equipment (including milking machine, pipe work) after each milking event. The milk cooling tanks are disinfected after each milk pick-up (i.e every 2-3 days). The system is flushed with clean water after disinfection to remove any residues of the product.

The emission pathway depends on the size of the farm. In bigger farms, cows are milked in so-called milking carrousels which are usually located next to the stable and which are

connected to the sewer system. In small farms, cows are milked in the stable using transportable milking equipment. In this case, emission occurs in modern farms to the sewer system, in older farms, without connection to the sewer system, to the manure. The tendency is definitely to separate the waste water stream coming from the milking parlours from the manure storage system since a substantial amount of water is used for cleaning, disinfection and subsequent flushing of the milking equipment which would lead to a high water contribution to the manure storage tank. Based on this information, it is assumed that the waste water from the milking parlour system is mainly released to the sewer system. This is also conform the ESD for PT4 for this scenario (Emission Scenario Document for Product Type 4, Disinfectants used in food and feed areas, 2011, p 24) and in agreement with the approach in the Assessment Report for the active substance for this scenario (PT4c). However, dairy farms are not necessarily connected to the municipal sewer and domestic waste may be purified on-site by individual sewage treatment plants. Considering that these systems are small (a few cubic meters), high loads of product residues may kill the microbial population instantly, resulting in malfunctioning of the plant. Therefore, to prevent malfunctioning of an on-site wastewater treatment system an RMM was set.

According to the recent version of TAB (ENV A13, version 2.1, December 2019), the assessment of the emission via manure also needs to be performed for disinfectants used in milking parlour systems using the available emission scenarios from the ESD for PT 3. The TAB entry was not available before the submission of this application and thus it was not taken into account in the risk assessment. Complete degradation of the sodium hypochlorite during manure storage can be expected. Therefore, the risks for this pathway can be considered covered by the conclusions for STP.

Scenario: Disinfection of milking parlour systems (Disinfection of milking systems and bulk tanks on farms by professional users)

Input parameters for calculating the local emission				
Input	Symbol	Unit	Value	Remarks
Scenario: *PT4-Disinfection of milking parlour systems*				
Concentration of active substance in the product	C_{form}	g/L	826	Highest in-use concentration
Application rate of biocidal product used for cleaning of the milking installation	$V_{form,inst}$	L/d	130	Default value ESD PT4 (2011)
Application rate of biocidal product used for cleaning of the milk storage tank	$V_{form,tank}$	L/d	45	Default value ESD PT4 (2011)
Fraction of the product disintegrated during application	F_{dis}	-	0	Default value ESD PT4 (2011)
Fraction released to waste water	F_{water}	-	1	Default value ESD PT4 (2011)
calculation: Elocalwater= $[C_{form} \bullet V_{form,\ inst} + V_{form,\ tank}] \bullet (1 - Fdis) \bullet (1 – Felim) \bullet Fwater/ 1000$				
Emission rate to wastewater (standard STP)	[kg/d]	0.145		

Fate and distribution in exposed environmental compartments

The fate and behaviour of active chlorine in the environment is described in detail in the CARs of sodium hypochlorite and active chlorine. Hypochlorite is a highly reactive compound, which reacts rapidly with organic matter in the sewer, STP, surface water and soil. Where organic and nitrogenous materials are present, hypochlorite acts as a highly reactive oxidizing agent. It reacts rapidly with organic matter in sewage or activated sludge and most (≈ 99%) of the available chlorine is converted to inorganic chloride. Oxidation is probably the predominant chemical reaction occurring in chlorine's disinfection processes. Furthermore, circumstances influencing the reactivity of hypochlorite are time, temperature, pH and the availability of amount and type of organic matter. The content of organic matter in soil is lower than in sewage or activated sludge but it is high enough to ensure complete decomposition in a relatively short time.

Degradation in the sewer system:

The kinetic model of Vandepitte and Schowanek (sodium hypochlorite CAR, doc IIIA) shows that hypochlorite is eliminated during transport in the sewer within the first minutes. Therefore, degradation of hypochlorite in the sewer system was considered in the emission estimation, using the estimated half life of < 20 seconds (25°C, recalculated to 56 seconds at 12°C) of the kinetic model, as degradation rate.

A sewer residence time of 1 h, proposed as default value in the ESD for PT5, was assumed. The value of 1 hour is based upon an average distance of 4.5 km from the point of release to the STP and an estimated flow rate of 1.5 km in 20 minutes in the municipal canal sewer system.

The degradation of hypochlorite in the sewer system was calculated, assuming first order kinetic, using the following equation:

Calculation: $M_{t1} = M_{t0} * EXP^{(-k * t1)}$ M_{t1} = total amount of substance present at time 1 [kg/d] M_{t0} = total amount of substance at time 0 [kg/d] (= 0.145 kg/d) k = rate constant (k = 44.6 h^{-1}, calculated from the DT50 at 12°C: ln2/DT50) t1 = time [h] (= 1 h)	= 4.48 E-21 kg/d

The amount of hypochlorite that is theoretically emitted to the STP after one hour residence time in the sewer was calculated to be 4.48 E-21 kg/d.

Usually modern farms are connected to the sewer system and therefore emission occurs directly to the sewer system and indirectly to freshwater and sediment via treated wastewater. Emission to soil (and groundwater) are in principle possible via the application of sewage sludge from the STP.

Identification of relevant receiving compartments based on the exposure pathway					
Representative scenario	STP	Freshwater incl. sediment	Marine	Soil incl. groundwater	Air
PT4					
Disinfection of milking parlour systems (discharge via STP)	Q	Q	-	Q	Q

Q will be assessed qualitatively for both active substance and chlorate

2.2.9.3 Risk characterisation

Considering the fast degradation in the sewer system, the emission to the STP will be negligible. As shown in the Assessment Report of the active substance, a qualitative risk assessment for the free available chlorine species (FAC), given the very low PEC/PNEC values (≈ 0) for the active substance with a similar product (Scenario PT4c - Disinfection of milking parlour systems), when taking into account degradation in the sewer. Although the use concentration of the product in the Assessment report was 600 mg/L active chlorine, which is almost 1.5x lower than the use concentration of Super (826 mg/L active chlorine), all PEC/PNEC values will evidently still be <<< 1 for all compartments. Due to the fast degradation, it is very unlikely that any hypochlorite will reach the groundwater because hypochlorite rapidly degrades in sewer, sewage sludge and soil. Therefore, the risks for the STP, freshwater incl. sediment and soil incl. ground water compartment are considered acceptable.

Hypochlorite might enter the atmosphere due to volatilisation from the STP. Exposure assessment in the AR showed that emission to air via this pathway is negligible. Given the adsorption of hypochlorite to aerosol particles, the volatilisation from water into air and the adsorption of hypochlorite onto soil are very low, thus hypochlorite will remain in the aqueous phase and degrade very rapidly. Exposure to air is thus not considered. There are no indications that active chlorine contributes to depletion of the ozone layer as it is not listed as ‘controlled substance’ in Annex I of Regulation (EC) No 1005/2009 of the European Parliament. Therefore, the risks for the air compartment are considered acceptable.

Primary and secondary poisoning

Active chlorine does not bioaccumulate and does not concentrate in the food chain. The low BCF indicates that the risk for birds and mammals is low regarding secondary poisoning. For the proposed use with no direct release into the environment, direct exposure of birds and mammals is considered negligible. Hence the product meets the standards for the risk to birds and mammals. Primary poisoning is not expected for the intended uses of Super.

Mixture toxicity

Non-relevant for this product as the product contains only one active substance and none of the coformulants are of environmental concern.

Assessment of disinfection-by-products (DBPs)

According to the BPC opinion for active chlorine in PT4 the risk assessment for DBP should be performed in the product authorisation when guidance becomes available. Current guidance for DBP covers only halogenated disinfectants used in PT 2 and therefore assesment of disinfection by-products (DBP) is not included in the PAR.

Assessment of chlorate as an impurity

Chlorate is a by-product of the manufacturing process and can be formed during storage of products based on sodium hypochlorite. Chlorate is considered as a relevant metabolite in drinking water. Sodium chlorate has a harmonised classification for environment (Aquatic Chronic 2; H411) but the data supporting this classification has been re-evaluated. It is proposed in the recent CLH report (3.4.2020, under consultation 4.5.-3.7.2020) that the available data do not support a long-term hazard classification for the environment. Therefore, it is proposed in the draft CLH report that the current environmental classification should be removed. Considering that chlorate is less ecotoxic than the active substance and awaiting harmonised endpoints to be included in the CAR, the WG-I-2020 agreed that chlorate as an impurity can be assessed qualitatively for all the environmental compartments in on-going authorisations currently under assessment. In addition, the WG-I-2020 agreed that chlorate can be assessed qualitatively for the assessment of abstraction of drinking water from surface water.

Chlorate is a strong oxidizer and thus, it is assumed that it degrades in the environment. Valid readily biodegradability test (OECD TG 301 or OECD TG 302) results are not available for inorganic sodium chlorate. However, available studies on biodegradation of chlorate are referred in the recent CLH report indicating that chlorate reducing micro-organisms are present e.g. in the sewage, terrestrial ecosystems and freshwater. It is concluded in the CLH report that in applying a weight of evidence approach chlorate should be considered as rapidly degradable for classification purposes. The view of rMS is that this conclusion can be applied for this risk assessment also. There are no direct releases to the environment and wastewater from the intended use of Super products will be discharged via STP. Therefore, the understanding of the rMS is that no unacceptable risk for environment will be likely when chlorate is present as an impurity in the Super products.

According to the BPR Annex VI (point 69) the PEC for surface water must be compared with the maximum permissible concentrations laid down by Directive 2000/60/EC (Water Framework Directive, WFD) and Directive 98/83/EC (Drinking Water Directive) where the surface water in or from the area of envisaged use is intended for the abstraction of drinking water. No maximum permissible concentration for chlorate or a general value for pesticides in surface water is set in WFD, but for pesticides a maximum permissible concentration of 0.1 µg/L is set in current Drinking Water Directive. However, according to Drinking Water Directive this limit value applies to each individual organic pesticide and their relevant metabolites, degradation and reaction products. It was agreed at the BPC-34 that it is in principle acceptable to use the limit value of 0.1 µg/L to inorganic substances, provided that no substance specific values are in place and provided that the toxicological reference value is not lower (in line with paragraph 68 in Annex VI of BPR (EU) 528/2012). The WHO recommend a value of 700 µg/L for chlorate in drinking water. Drinking Water Directive has

been under revision and a specific maximum permissible concentrations (i.e. 250 µg/L or 700 µg/L depending on the use) have been proposed for chlorate. A provisional agreement was reached on Drinking Water Directive by the EU Council and the EU Parliament in December 2019. The provisional agreement is now subject to formal approval by the European Parliament and the Council. The proposed specific limit values are based on the latest scientific data and therefore the rMS is of the opinion that this information can be applied already before formal approval of Drinking Water Directive. As a conlusion, based on conclusion regarding biodegradation of chlorate in the recent CLH report, the opinion of rMS is that it is unlikely that the worst case specific limit value of 250 µg/L will exceed in the surface water when Super product is used according to the instructions.

Aggregated exposure (combined for relevant emmission sources)

The "Decision tree on the need for estimation of aggregate exposure" (Guidance on BPR, Vol. IV Part B+C) should be followed when performing the aggregate exposure assessment.

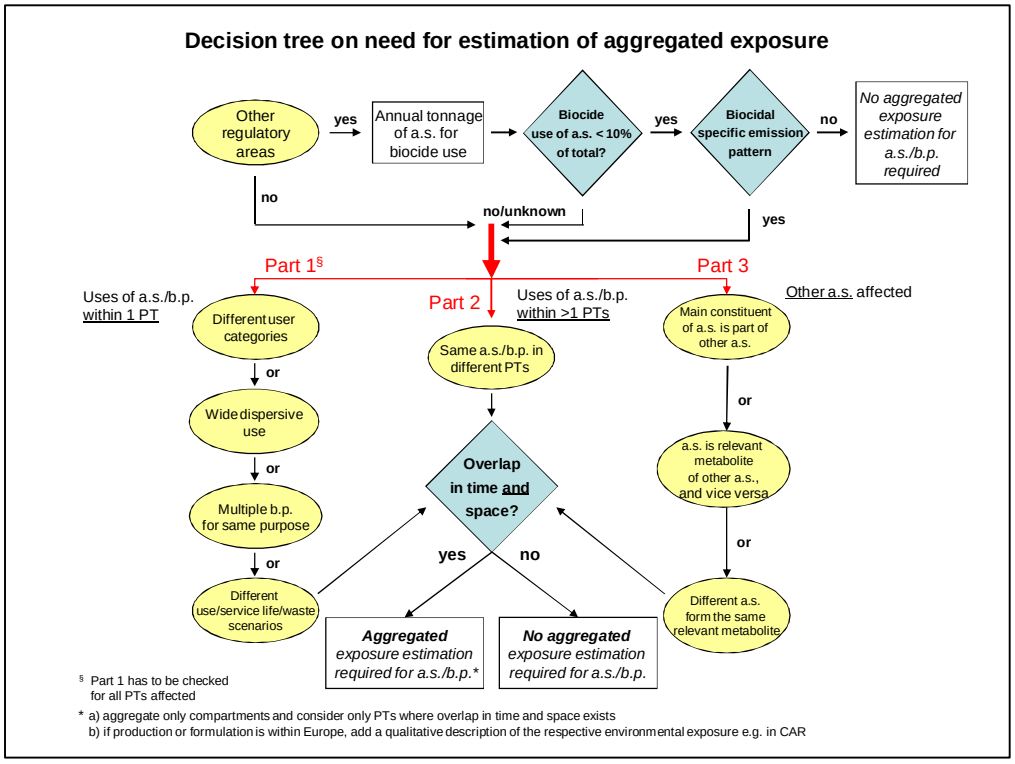


Figure 1: Decision tree on the need for estimation of aggregated exposure

Aggregated exposure assessment is not deemed necessary for Super (one PT, one type of user, one use).

The applicant also refers to the active substance Assessment report, where an aggregated risk assessment has been performed for active chlorine releasers in different PT's, with an acceptable outcome.

Overall conclusion on the risk assessment for the environment of the product
No unacceptable risk to the environment will occur following the use of the product Super.

2.2.10 Measures to protect man, animals and the environment

RECOMMENDED METHODS AND PRECAUTIONS

Storage: Store upright in the tightly closed original container. Protect from direct light, temperatures above 30°C and frost. If the product is frozen, thaw in a warm environment and mix well before use. Shelf-life: 9 months
Handling: As a rule, at least 10 air changes per hour are recommended at the workplace. Handle in accordance with good industrial hygiene and safety practice (e.g Keep away from food, drink and animal feedingstuffs. When using, do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the workplace. Regular cleaning of equipment, work area and clothing. Avoid contact with skin, eyes and clothing. Wear suitable gloves and eye/face protection.).
Precautionary phrases for Super related to handling:
P280 - Wear protective gloves/protective clothing/eye protection/face protection
Transport: UN-No 1719; Proper shipping name 1719 - Caustic alkali liquid, n.o.s (Sodium hydroxide, Sodium hypochlorite). Hazard Class 8. Packing Group III
Fire: Super is not flammable. As in any fire, firefighters should wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.
Specific hazards arising from the chemical: Thermal decomposition can lead to release of irritating gases and vapours. In the event of an explosion do not breathe fumes.
Suitable Extinguishing Media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment (Dry chemical, Carbon dioxide (CO2), Water spray, alcohol-resistant foam).
Disposal: Unused products and its packaging should be disposed in accordance with local regulations (P501).

IDENTITY OF RELEVANT COMBUSTION PRODUCTS IN CASES OF FIRE
Not applicable as Super is not flammable.

SPECIFIC TREATMENT IN CASE OF AN ACCIDENT
First-aid measures:
General Advice: Immediate medical attention is required. Show the safety data sheet to the doctor in attendance.
Eye contact: Immediate medical attention is required. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing.
Skin contact: Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes.
Ingestion: Immediate medical attention is required. Remove from exposure, lie down. Clean mouth with water and afterwards drink plenty of water. Do not induce vomiting. Never give anything by mouth to an unconscious person. Call a physician or Poison Control Centre immediately.
Inhalation: Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician or Poison Control Centre immediately.

Emergency measures to protect the environment
Prevent further leakage or spillage if safe to do so.
Methods and materials for containment and clean-up: Dam up. Collect spillage. Soak up with inert absorbent material. Prevent product from entering drains. Keep in suitable and closed containers for disposal.

POSSIBILITY OF DESTRUCTION OR DECONTAMINATION FOLLOWING RELEASE
The product use is not likely to lead to direct entry to the environment since the product is mainly used indoors in the milking parlour, above an impermeable floor. There is no direct release to air, soil or surface waters. Hence no procedures for destruction or decontamination have been developed.

PROCEDURES FOR WASTE MANAGEMENT OF THE BIOCIDAL PRODUCT AND ITS PACKAGING

There is no direct release to the environment when used according to instructions. Therefore, preliminary treatment of waste is not necessary. To prevent malfunctioning of an on-site wastewater treatment system, wastewater containing the product must be discharged to a municipal sewer. Unused product and its packaging should be disposed of in accordance with local regulations.The empty containers may not be recycled or re-used.

PROCEDURES FOR CLEANING APPLICATION EQUIPMENT WHERE RELEVANT
Not applicable, no application equipment.

SPECIFY ANY REPELLENTS OR POISON CONTROL MEASURES INCLUDED IN THE PRODUCT
Not applicable, Super does not contain any repellents or poison control measures.

2.2.11 Assessment of a combination of biocidal products

For biocidal products that are intended to be authorised for the use with other biocidal products: Not applicable

3 ANNEXES

3.1 List of studies for the biocidal product

N°	Reference type	Year	Title	Testing laboratory	Report no.	Owner company
1	Study report	2017	Physical/chemical properties of Super (Formulation 102)	West Agro Inc	FR 2017-PC-006	DeLaval NV
2	Study report	2018	Super stability	DeLaval NV	RA180335b	DeLaval NV
3	Study report	2017	Validation of an IC method for the quantification of the sodium chlorate content in the test item "Super"	Eurofins Biolab Srl	S-2017-03467	DeLaval NV
4	Study report	2018	Determination of the sodium chlorate content in the test item "Super"	Eurofins Biolab Srl	STULV18AA0457-1	DeLaval NV
5	Study report	2017	Persistent foam test of Super	DeLaval NV	/	DeLaval NV
6	Study report	2017	Dilution stability of Super	DeLaval NV	/	DeLaval NV
7	Study report	2018	Report dilution stability of SUPER	DeLaval NV	/	DeLaval NV
8	Study report	2018	Determination of Surface Tension on the Sample Super	Innovhub, Stazioni Sperimentali per l'industria	1801160	DeLaval NV
9	Study report	2017	Super: Determination of Flash Point	Envigo Research Limited	Report YT12QM	DeLaval NV
10	Study report	2012	Corrosion testing CLP Super F102	Belgian Welding Institute NPO	Report 12/001k	DeLaval NV
11	Study report	2018	Validation of Titration Method WM004: Determination of Available Chlorine in Super by Titration	DeLaval Manufacturing	/	DeLaval NV
12	Study report	2016	Suspension bactericidal effectiveness with skim milk solution as interfering substance on Super (Formulation 102)	Eurofins Biolab Srl	S-2016-01281 AM	DeLaval NV
13	Study report	2017	Suspension bactericidal effectiveness with skim milk solution as interfering substance on Super (Formulation 102)	Eurofins Biolab Srl	S-2016-04741 AM	DeLaval NV
14	Study report	2016	Suspension yeasticidal effectiveness with skim milk solution as interfering substance on Super (Formulation 102)	Eurofins Biolab Srl	S-2016-01282 AM	DeLaval NV
15	Study report	2017	Suspension yeasticidal effectiveness with skim milk solution as interfering substance on Super (Formulation 102)	Eurofins Biolab Srl	S-2016-04742 AM	DeLaval NV

16	Study report	2011	Super – Universal alka – (F102) – Assessment of acute dermal irritation	[redacted]	[redacted]	DeLaval NV
17	Study report	2012	Super – Universal alka – (F102) - Evaluation of Acture Oral Toxicity in Rats - Acute Toxic Class Method			DeLaval NV
19	Study report	2012	Super – Universal alka – (F102) - Evaluation of acute dermal toxicity in rats			DeLaval NV
20	Study report	2018	BPR chlorinated products residue trial Super	Eurofins Food Testing	2017-038-Super	DeLaval NV
21	Report	2020	Additional information for the BPR registration of Super	DeLaval NV	RA200013a	DeLaval NV

3.2 Output tables from exposure assessment tools

Excel file with the calculations made for the professional exposure and the dietary exposure.

Calculations human risk assessment.xlsx

3.3 New information on the active substance

Not applicable, no new information on the active substance is provided.

3.4 Residue behaviour

No new information on the active substance is provided.
With regards to the impurity chlorate:
Appendix 1 (confidential) includes the field trial residue report, for which data are used in the Human (consumer exposure) risk assessment.

Appendix 1-2017-023 BPR chlo

3.5 Summaries of the efficacy studies (B.5.10.1-xx)

Not applicable, already provided in 2.2.5.5 and IUCLID.

3.6 Confidential annex

See a separate document.

3.7 Other

Not applicable.